The mean age of study participants was 65 years; 445 patients (89%) were treated with intravenous tissue plasminogen activator before randomization. Retrievable stents were used in 190 patients (81.5%) assigned to intra-arterial treatment. The 90-day modified Rankin scale (mRS) score—the primary outcome measure—showed a significant difference in favor of the intervention versus the control in analysis with univariable ordinal regression.

Dr Nour and colleagues sought to quantify the magnitude of the effect of the clinical improvement with intra-arterial treatment in MR CLEAN, using the size metrics of NNTB, NNTH, and the benefit per hundred (BPH) and harm per hundred treated.

They analyzed the magnitude of effect of the transitions across multiple mRS levels and for individual dichotomizations of the mRS. The following 3 analysis methods were used: joint outcome algorithmic specification, permutation analysis (Mann-Whitney test), and expert-dependent joint outcome analysis using 8 independent experts (3 stroke neurologists, 1 interventional neurologist, 2 interventional neuroradiologists, and 2 endovascular neurosurgeons).

As calculated by the absolute risk reduction in the dichotomized analysis (Table 1), the best NNTB was 6.6 and the best net BPH was 15, whereas the other 3 methods of analysis produced a much lower NNTB but a much higher BPH (Table 2).

When the results are considered together, the use of endovascular therapy compared with medical therapy alone will result in 1 of 7 treated patients not having a disability and 1 of every 3 to 5 treated patients having a lesser degree of disability, said Dr Nour. Among 100 patients treated with endovascular therapy, 15 will not have a disability and 23 to 32 will have a lesser degree of disability compared with that of patients treated with medical therapy.

This analysis of the magnitude of the treatment effect in MR CLEAN provides useful information for patients, caregivers, and physicians involved in acute stroke care, she concluded.

Table 1. NNTB and BPH in Dichotomized Analysis

Modified Rankin Scale	Absolute Risk Reduction, %[a]	NNTB	BPH
0 vs 1-6	3	33.3	3
0-1 vs 2-6	6	16.7	6
0-2 vs 3-6	14	7.1	14
0-3 vs 4-6	15	6.6	15
0-4 vs 5-6	7	14.3	7
0-5 vs 6	1	100	1

BPH, benefit per hundred; NNTB, number needed to treat to benefit.

[a]Absolute risk reduction percentages presented on behalf of the MR CLEAN investigators at World Stroke Conference, October 2014.

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Table 2. Comparison of Magnitude of Treatment Outcomes

Method of Analysis	NNTB	BPH
Dichotomized	6.6 ↔ 100	15 ↔ 1
Joint outcome table algorithmic specification	3.2	31.5
Permutation analysis	3.4	29
Joint outcome table expert dependent	4.5	22.6

BPH, benefit per hundred; NNTB, number needed to treat to benefit.

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MR CLEAN: Intra-arterial Intervention in Stroke Patients Is Safe and Effective

Written by Alla Zarifyan

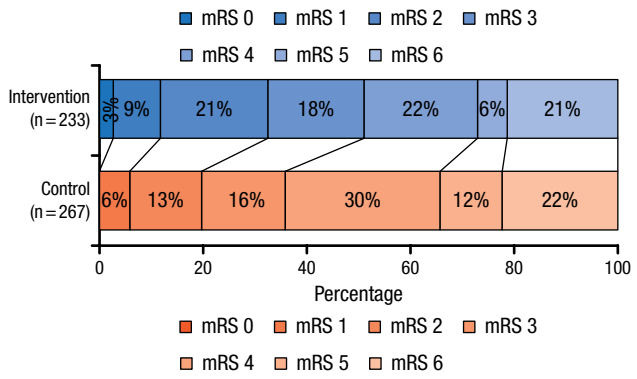
Yvo B. Roos, MD, PhD, University of Amsterdam, Amsterdam, the Netherlands, presented the results from the MR CLEAN trial [Berkhemer OA et al. *N Engl J Med*. 2015], which demonstrated, for the first time, the safety and efficacy of intra-arterial treatment within 6 hours of stroke onset in patients with acute ischemic stroke caused by intracranial anterior circulation occlusion.

MR CLEAN was a multicenter, randomized, prospective, open-label, phase 3 trial with blinded assessment conducted in the Netherlands. Eligible patients were aged ≥18 years with a National Institutes of Health Stroke Scale (NIHSS) score of ≥2, who had an acute ischemic stroke due to intracranial anterior circulation occlusion and received treatment within 6 hours from stroke onset.

Intra-arterial intervention consisted of arterial catheterization with a microcatheter to the level of the intracranial arterial occlusion, followed by delivery of a thrombolytic agent, mechanical treatment, or both (the method was left to the discretion of the treating physician). The primary outcome was the score on the modified Rankin Scale (mRS) at 90 days. Secondary outcomes included neuroimaging of arterial recanalization at 24 hours and the final infarct volume at 7 days.

The study enrolled a total of 500 patients (233 in the intervention group, 267 in the control group). The main clinical characteristics, including the mean age

Figure 1. mRS Score Distribution at 90 Days



mRS, modified Rankin Scale.

From *N Engl J Med*, Berkhemer OA et al, Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke, 2015;372:11-20. Copyright © Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

and NIHSS score, at baseline were similar between the groups. Intra-arterial therapy was performed in 196 of the 233 patients within the intervention group. Retrievable stents were used in 190 of these patients (97%), other devices were used in 5 patients (2.6%), and only 1 patient (0.4%) received thrombolytic treatment alone.

The primary outcome analysis revealed that there was a shift in the distribution of the mRS scores at 90 days in favor of the intervention (OR, 1.67; 95% CI, 1.21 to 2.30), which was consistent for all mRS categories except death (Figure 1). The distribution of mRS scores of 6 (death) were similar in both groups.

Computed tomographic angiography at 24 hours demonstrated that residual occlusion at the target site could not be detected in 75.4% of patients in the intervention group vs 32.9% in the control group (OR, 6.9; 95% CI, 4.3 to 10.9). The between-group difference in the final infarct volume at 7 days also favored the intervention group (19 mL; 95% CI, 4 to 34). The NIHSS score at 7 days was, on average, 2.9 points lower in the intervention group than in the control group (95% CI, 1.5 to 4.3). Prespecified subgroup analyses demonstrated that the treatment effect remained consistent regardless of age, NIHSS score, time from onset to randomization, and other criteria.

There was no significant difference between the intervention and the control group in the occurrence of serious adverse events, such as parenchymal hemorrhage type 2, pneumonia, and hemicraniectomy. The only notable difference was a higher incidence of new ischemic stroke in different vascular territory in the intervention group (5.6%) vs the control group (0.4%); however, according to Prof Roos, that is an expected adverse effect of mechanical intervention.

Solitaire Stent Reduced Disability in Stroke Patients in the SWIFT PRIME Trial

Written by Alla Zarifyan

Jeffrey L. Saver, MD, University of California, Los Angeles, California, USA, reported results from the Solitaire With the Intention for Thrombectomy as Primary Endovascular Treatment [SWIFT PRIME; NCT01657461] study, demonstrating that endovascular treatment with a removable Solitaire stent in combination with intravenous tissue plasminogen activator (IV tPA) was safe and effective at significantly lessening poststroke disability after an acute ischemic stroke with emergent large vessel occlusions in anterior circulation.

Currently, IV tPA is the only Food and Drug Administration–approved, beneficial pharmacologic therapy for patients with an acute ischemic stroke. However, according to Dr Saver, it has several limitations, and endovascular neurothrombectomy presents a promising complimentary reperfusion strategy. Previously, use of the Solitaire stent was reported to be associated with more frequent and faster reperfusion, reduced intracerebral hemorrhage, and better disability outcomes [Pereira VM et al. *Stroke*. 2013; Dávalos A et al. *Stroke*. 2012; Saver JL et al. *Lancet*. 2012].

SWIFT PRIME was a multicenter, international, prospective, randomized, blinded end point study of the Solitaire stent in combination with IV tPA vs IV tPA alone within 6 hours of symptom onset in patients experiencing an acute ischemic stroke due to large vessel occlusion. The primary end point was an evaluation of disability measured by modified Rankin Score (mRS) at 90 days. Study success criteria were a more favorable mRS distribution in the Solitaire plus IV tPA arm and a substantial difference in the number of patients achieving an mRS of 0 to 2 at 90 days.

The study enrolled a total of 196 patients (98 per arm). All baseline characteristics including demographics, disease severity, medical history, and physiologic characteristics were well matched between the treatment arms.

The study met its primary end point with significantly more patients treated with Solitaire plus IV tPA showing less disability ($P = .0002$). For the secondary clinical end points, the trial demonstrated that 60.2% of patients treated with Solitaire plus IV tPA achieved functional independence (mRS of 0 to 2) at 90 days vs 35.5% of patients treated with IV tPA alone ($P = .0008$). However, death at 90 days was not statistically significant, with 9.2% of patients dying in the Solitaire plus IV tPA arm vs 12.4% in the IV tPA arm ($P = .5$). Subgroup analyses