

16 grams  $MgSO_4$  or matched placebo was given over 24 hours. Patient demographics and baseline characteristics are shown in Table 1.

Table 1. Demographics and	<b>Baseline Characteristics of</b>
FAST-MAG Patients.	

Age; mean years (range)	70 (40-95)		
Gender (%) Male	58		
Ethnicity (%) Hispanic	22		
Race (%) White Black Asian Pacific Islander	80 11 6 2		
Stroke Severity (range) LAMS <sup>1</sup> NIHSS <sup>2</sup>	4.0 (1-5) 9.0 (0-40)		
Stroke Subtype (%) Cerebral Ischemia Ischemic Stroke TIA Intracerebral hemorrhage Stroke Mimic	72 62 10 23 4		
Concomitant Therapy (%) IV TPA <sup>3</sup>	28		

<sup>&</sup>lt;sup>1</sup>Prehospital; <sup>2</sup>At hospital arrival and after treatment starts; <sup>3</sup>Among all cerebral ischemia patients.

The median time to study drug initiation from stroke onset was 46 minutes, the mean time of paramedic arrival to drug initiation was 30 minutes, and mean time from paramedic arrival and the patient's arrival in the emergency department was 35 minutes. Treatment was initiated within 1 hour of stroke onset in 73% and between 1 to 2 hours in 25% of patients. The primary study endpoint is the modified Rankin Scale (mRS) score, assessed 3 months poststroke. The Cochran-Mantel-Haenszel test will be used to compare outcomes between the MgSO<sub>4</sub> and placebo treatment groups. These results will be presented in a future report.

Dr. Saver concluded that prehospital administration of neuroprotective agents substantially reduces on-sceneto-needle time. He listed a number of innovative firsts for the FAST-MAG trial: first "golden" hour (<1 hour) stroke treatment trial; first acute (<3 hr) neuroprotective stroke treatment trial; first trial of neuroprotective drugs before recanalization therapies; first prehospital stroke RCT; and first prehospital RCT for any condition that employed physician-elicited informed consent.

## Dramatic Early Improvement in the NINDS Trial: Better 90 Day Outcomes and No Increased Rates of Intracranial Hemorrhage

NIHSS baseline score and time to treatment <90 minutes are independent predictors of dramatic early response to rt-PA therapy. The occurrence of intracerebral hemorrhage (ICH) is similar between dramatic and nondramatic responders.

Clinical experience demonstrates that a certain percentage of patients with acute ischemic stroke improve rapidly after the administration of IV-rtPA [Felberg RA et al. *Stroke* 2002]. Although research in a small number of patients has pointed to the development of subtypes of mild hemorrhage as a marker for early recanalization and good clinical outcomes at 90 days (OR, 10.9) [Molina CA et al. *Stroke* 2002], anecdotal clinical experience has suggested a potential relationship between dramatic early improvement and posttreatment symptomatic ICH.

Jordan Bonomo, MD, University of Cincinnati, Cincinnati, OH, reported on the results of a retrospective study that used data from the rt-PA arm of the National Institute of Neurological Disorders (NINDS) trial [Kwiatkowski TG et al. *New Engl J Med* 1999] to evaluate dramatic early improvement after treatment with IV-rt-PA as a risk factor for the development of posttreatment ICH. A secondary objective was to characterize the subgroup of patients with dramatic early improvement.

Demographics, baseline clinical characteristics, rates of ICH, and outcomes were compared between subjects with and without dramatic improvement. Dramatic improvement was defined as either NIHSS  $\leq 2$  at 2 hours or a 10-point improvement from baseline at 2 hours after initiation of therapy [Alexandrov et al. *Stroke* 2000]. Logistic regression was used to predict posttreatment ICH, as well as good clinical outcome at 90 days (mRS 0-1).

Of the 312 patients who were treated with IV-rt-PA, 65 (20.8%) had dramatic early improvement and 246 (78.8%) did not. Early dramatic improvement was strongly associated with good clinical outcome at 90 days (78% dramatic responders vs 33% of nondramatic responders; p<0.0001). NIHSS baseline score and time to rt-PA therapy <90 minutes were the only independent predictors of early dramatic improvement. The occurrence of ICH by 36 hours



(both symptomatic and asymptomatic) was not significantly different (p=0.27) between the dramatic (4/65; 6.2%) and nondramatic improvement (29/246; 11.8%) groups. After adjustment for dramatic improvement, age, and CT edema, only CT mass effect and baseline NIHSS were predictive of symptomatic ICH in dramatic improvers. Age, baseline NIHSS, and dramatic improvement were independent predictors of good outcome at 90 days (Table 1).

 Table 1. Predictors of Rapid Response, sICH in Rapid

 Responders, and Outcome.

Variable	Odds Ratio	95% CI	p Value	
Predictors of Rapid Response <sup>1</sup>				
Baseline NIHSS	0.94	0.91-0.98	p=0.006	
tPA ≤90 minutes	2.16	1.21-3.85	p=0.009	
Predictors of sICH with Rapid Improvement <sup>2</sup>				
Baseline CT Mass Effect	7.01	0.95-51.95	p=0.06	
Baseline NIHSS	1.08	1.01-1.15	p=0.02	
Predictors of Outcome <sup>3</sup>				
Age	0.95	0.93-0.98	p=0.002	
Baseline NIHSS	0.84	0.80-0.88	p<0.0001	
Dramatic Improvement	8.69	4.01-18.82	p<0.001	

1. Covariates were: age, serum glucose, systolic blood pressure, time after onset to admission and treatment

2. Adjusted for dramatic improvement, age, and CT edema

3. Covariates included: prior stroke, baseline systolic blood pressure, serum glucose, and time to treatment

sICH= symptomatic intracerebral hemorrhage

## How Safe is Intracranial Angioplasty and Stenting? Lessons Learned from 188 Interventions

Angioplasty appears to be safer than stenting for endovascular revascularization in patients with intracranial atherosclerosis and results in a lower stroke risk.

Results of the Warfarin–Aspirin Symptomatic Intracranial Disease (WASID; NCT00004728) study suggested that patients with stroke as their qualifying event and a 70% to 99% stenosed lesion had a 1-year stroke rate of 22.5%. The objective of a study presented by Firas Al-Ali, MD, Borgess Medical Center, Kalamazoo, MI, was to compare the safety and efficacy of endovascular revascularization for intracranial atherosclerosis to determine if it is possible to reduce the risk of stroke that was seen in the WASID study.

This was a retrospective analysis of prospectively collected data from a single center. Data collection included success rate, complication rate within 30 days, restenosis rate, and stroke rate at 1 year postintervention.

Data were available for 138 patients with >70% stenosis. Of these, 50 patients underwent 59 primary angioplasties on a total of 58 lesions. A total of 88 patients with 98 lesions underwent 99 primary stenting procedures. Wingspan Stent (WSS<sup>TM</sup>) was used for 55 patients, and a balloonmounted stent (BMS) was used in 33 patients. Three patients had both types of stents for different vessels.

The success rate in the angioplasty group was 94.9%. Three of the 59 primary angioplasty procedures required immediate stenting for a large dissection, and 3 were associated with complications (2 minor strokes and 1 groin infection) within the first 30 days. Imaging follow-up was available for 41/58 lesions. Overall, 43% of the lesions required a second intervention or had a vascular occlusion/near-occlusion. Clinical follow-up (mean 31.7 months) was available for 46 patients. There were 2 strokes—1 in the same vascular territory and 1 in a different vascular territory.

The success rate for primary stenting was 96.6% for the WSS group and 97.4% for the BMS group. Within the BMS group there were 6 periprocedural complications, 4 of which were strokes. Of these, there were 3 in the basal artery that resulted in significant deficit (mRS 2, 3, and 4). One patient had a vessel perforation. Imaging follow-up was available for 28 patients/vessels. Restenosis (<40%) occurred in 1 patient. Clinical follow-up (mean 17.6 months) was available for all 33 BMS patients. There were 3 strokes, 2 of which resulted in death, felt to be due to in-stent thrombosis. The mortality rate at 1 year for the BMS group was 9.1%.

Within the WSS group, there were 12 periprocedural complications; none was fatal. Two were subarachnoid hemorrhage. Of these, 1 (distal microwire perforation) was significant, with an mRS of 3 at the 1-year follow-up. The other was minimal and related to a microtear from the angioplasty balloon, which was well controlled by with stent placement. One patient presented intraparenchymal hematoma 3 days after stenting but was asymptomatic at 2 weeks. There were 8 ischemic strokes, of which 2 were significant and required inpatient rehabilitation. Six were minor, wherein the patient returned to normal in <1 week. Imaging follow-up was available for 42/59 vessels. Overall, 28.4% of patients had occlusion or needed reangioplasty. Clinical follow-up (mean 6.7 months) was available for 40 patients. There