(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[1]			
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[2]			
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[3]			
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™) was used for 55 patients, and a balloon-mounted 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 stent placement. One patient presented with 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

were a total of 3 ischemic strokes within 1 year (7.5%). Two patients had minor strokes that resolved completely. One patient had a major (mRS 4) stroke.

The Results of NEST-2: A Double-Blind, Randomized, Phase III Study Evaluating the Safety and Efficacy of Transcranial Laser Therapy for Acute Ischemic Stroke within 24 Hours of Stroke Onset

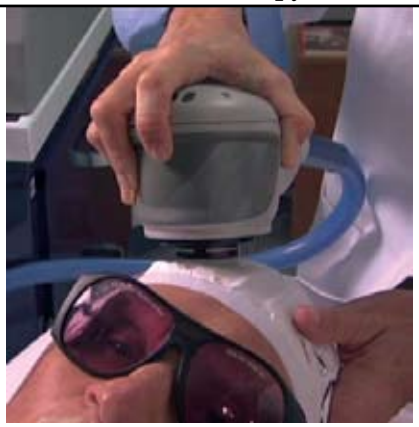
Results from the NeuroThera® Effectiveness and Safety Trial-2 (NEST-2; NCT00419705) show no difference in efficacy between transcranial laser therapy (TLT) and sham treatment for the treatment of acute ischemic stroke (AIS) when applied within 24 hours of diagnosis.

The NeuroThera® Effectiveness and Safety Trial-2 (NEST-2) was a phase III prospective, double-blind, randomized, sham-controlled, multicenter (n=58) study of TLT for the treatment of AIS. The study population included subjects, aged 40 to 90 years, with an NIHSS score of 7 to 22 who were diagnosed with AIS. Evidence of intracranial, subdural, or subarachnoid hemorrhage was cause for exclusion, as were prestroke mRS score ≥3; blood glucose >400 mg/dl or <60 mg/dl; and sustained systolic blood pressure (BP) >190 mm Hg or <80 mm Hg, or diastolic >110 mm Hg or <50 mm Hg. Subjects who had received thrombolytic therapy (tPA) and those with head implant (eg, clipped aneurysm, Hakim valve) also were excluded. Subjects were followed for 90 days.

The primary efficacy endpoint was a modified Rankin Scale (mRS) score of ≤2 at 90 days. Secondary endpoints were the shift in mRS score and NIHSS score 0 or 1 at 90 days *or* an improvement of ≥9 points. Safety endpoints included mortality, adverse events, and intracerebral hemorrhage.

Subjects were randomly assigned to receive TLT (n=331) or sham treatment (n=327). Treatment was performed at 20 locations for 2 minutes each. For patient comfort and to avoid breaking the blind, the lens was mildly refrigerated. Median NIHSS score at baseline was 12 in the treatment group and 13 in the sham group. Mean time to treatment was approximately 14 hours in both groups (Figure 1).

Figure 1. Transcranial Laser Therapy with NeuroThera®.



*Subject presented is actor and not actual patient

- **20 locations for 2 minutes each**
- **Treatment regimen is the same regardless of stroke location**
- **808 nm wavelength is infrared and invisible**
- **Power 10 mW/cm^2**
- **Lens is mildly refrigerated for patient comfort and blinding**

NeuroThera® System is Limited by Federal Law to Investigational Use Only

There was no difference in the primary outcome of mRS score ≤2 (36.3% in the TLT group and 30.9% in the sham group; p=0.094). Adverse events were similar in both groups (Table 1). The shift in mRS score in the treatment group was equal to or better than in the sham population for mRS 0-4; however, there was no difference at the upper end of the score (mRS 5,6).

Table 1. Safety Results.

	TLT (n=331)	Sham (n=327)
90 day mortality	17.5%	17.4%
Serious adverse events	37.8%	41.8%
Intracerebral hemorrhage	14.8%	17.1%
Nervous system disorders	15.4%	15.5%
Respiratory disorders	10.6%	9.8%
Infections	7.6%	9.5%
Cardiac disorders	6.6%	7.9%