

## Sorting out major brain stent study: Experts say procedure effective for some patients

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An article appearing in the Sept. 7 *New England Journal of Medicine*, reporting on National Institutes of Health research on brain stents, says aggressive medical treatment without stenting is better for high-risk stroke patients.

But experts at Cedars-Sinai Medical Center who were involved in the study believe this procedure is appropriate for some patients. They express concern that those who might benefit from minimally invasive placement of a mesh tube or stent to open blocked <u>brain</u> arteries may be discouraged by this report. They say this study is a helpful start but not likely to be the final word on understanding when <u>stenting</u> may be appropriate, and raise concerns about several study limitations and exclusions.

"Patients in the trial received aggressive management of their <u>risk</u> <u>factors</u> – far greater than patients usually get. Only with such heroic measures will the average patient benefit the way those in the trial did," says Patrick D. Lyden, MD, chairman of the Department of Neurology and the Carmen and Louis Warschaw Chair in Neurology at Cedars-Sinai, an expert in the medical intervention and management of stroke.

Michael J. Alexander, MD, professor and clinical chief of the Department of Neurosurgery, and director of the Cedars-Sinai Neurovascular Center, comments: "For certain patients – particularly those for whom drugs are not effective – most experts believe stenting is a viable option. We have had many patients who have had dramatic,



immediate improvement in neurologic function following intracranial stenting."

Lyden and Alexander, who led Cedars-Sinai's part of the 50-center clinical trial, expressed concerns about this study including:

- Sicker patients such as those with multiple blockages of the arteries or long-length blockages were excluded; these are among patients most likely to benefit from stenting.
- Most patients in the trial had blockages in smaller arteries, which are more difficult to treat with stenting.
- It is common in clinical trials of interventional or surgical procedures for patients in the treatment arm to have a higher "event rate" in the first 30 days. Long-term results provide more valid information.

"Angioplasty and stenting procedures have become commonplace in treating blocked heart arteries, but stenting in the brain is more challenging because brain arteries are more delicate than those of the heart," said Alexander, a member of the initial NIH steering committee for this study. The Wingspan stent – evaluated in the study – was designed to be more flexible to accommodate fragile brain <u>arteries</u>.

"This is the first study which closely has analyzed longer-term patient outcomes with intracranial stenting. Initial studies with coronary (heart) artery stenting and carotid artery stenting also were not greatly successful. However, as we have been able to determine which <u>patients</u> are the best candidates for these treatments, and the technology has improved, they have become very successful. I believe the same will be true of intracranial artery stenting," Alexander said.

Alexander has performed more than 500 intracranial stenting procedures



and was involved in early testing of the device used in the study, the Gateway-Wingspan intracranial angioplasty and stenting system. He is a consultant and device proctor for Stryker Neurovascular, manufacturer of the Gateway balloon and Wingspan stent. He has no other financial interest in the company.

## Provided by Cedars-Sinai Medical Center

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