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## Yale-New Haven Hospital selected for evaluation of novel intracranial stent

Every 45 seconds a person in the United States suffers a stroke. More than 70,000 strokes in the U.S. each year are related to intracranial atherosclerotic disease (ICAD), a narrowing of the arteries in the brain due to plaque buildup. Stroke is a major cause of chronic disability and the third leading cause of death, right behind heart disease and cancer.

The U.S. Food and Drug Administration recently approved a study for the first balloon expandable stent for intracranial atherosclerotic disease in the United States. Yale-New Haven Hospital is one of only 30 sites selected internationally to participate in a trial to determine clinical outcomes in patients treated with this novel stent.

The trial, called the Vitesse Intracranial Stent Study for Ischemic Therapy, is a prospective, randomized, multicenter international trial. It compares the clinical outcomes of patients with cerebral ischemia due to stenosis in an intracranial artery treated with medical therapy alone or medical therapy plus intracranial stent. The Yale-New Haven principal investigator is Ketan R. Bulsara, MD, one of a very select group of neurosurgeons in the United States who is dual fellowship-trained in endovascular neurosurgery and neurovascular/skull base microsurgery. YNHH anticipates beginning this trial in the near future.

The need to develop more effective treatment options for patients with intracranial atherosclerotic disease was highlighted by the Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) study. The WASID study found that warfarin (also known as Coumadin), and aspirin provided similar stroke protection, but aspirin was associated with a lower risk of hemorrhage and related complications.

The WASID study also found that patients who recently had a stroke or TIA and suffered a cranial artery blockage of 70 percent or higher had a 22 percent chance of having another stroke within the first year, regardless of which medication was used. While the objective of the WASID trial was to compare the two drugs, results of the medication study also provide a baseline against which other therapies can be compared.

According to one of the WASID study authors, treatment options for stroke patients with severe blockage are extremely limited.

What the News Means to You

**Ketan R. Bulsara,  
MD**



### Stent's unique nature may be major advance

The findings of the WASID study forced the medical community to rethink treatments for patients with intracranial atherosclerotic disease. It raised significant concerns about the established treatment, anticoagulation with warfarin (Coumadin). The need to develop better treatments for patients with ICAD has been an ongoing process.

Though medication has always played a central role in treating patients with ICAD, there are high failure rates. In the 1980s there was considerable enthusiasm about microsurgical bypass procedures to improve intracranial blood flow. Unfortunately, this did not turn out to be a good option for these patients, as reported in a multicenter trial that was published in the *New England Journal of Medicine* in 1985.

In 2006, the FDA approved the Wingspan™ stent under an investigational device study for the treatment of ICAD. This first generation stent has generated attention due to its short-term promising results.

This past year, the first Wingspan stents were deployed at Yale-New Haven Hospital. The availability of this new technology is offering a treatment alternative for many patients who have failed all other options.

The Vitesse intracranial stent represents the second generation of stents approved for intracranial atherosclerotic disease. It is the first balloon-expandable stent approved for stroke and stroke-related conditions of the brain. The unique nature of this stent may represent a major advance in the treatment of symptomatic intracranial atherosclerotic disease.

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*Dr. Bulsara is director of neuroendovascular and skull base surgery at Yale-New Haven Hospital and assistant professor of neurosurgery at Yale School of Medicine.*