Middle Cerebral Artery Stenosis: Stenting Is One of the Options

No

Scott E. Kasner, MD

There is no doubt that stenting can widen a narrowed intracranial artery. However, serious questions remain about the role of this intervention in clinical practice. Medical technology often leaps into practice ahead of the evidence needed to support its widespread application. This is particularly common with new devices, which are not required to have demonstrated efficacy or safety with the same rigor as new medications. Moreover, they are not required to be superior to existing therapies. This is a flaw in the US regulatory system, and the premature approval of devices under humanitarian device exemptions often results in a “shoot first, ask questions later” approach that hampers subsequent attempts to determine whether these devices are actually beneficial.

The Warfarin versus Aspirin for Symptomatic Intracranial Disease (WASID) trial, the only large prospective study of intracranial stenosis, showed that patients with a stroke or transient ischemic attack attributable to ≥50% stenosis of a major intracranial artery (internal carotid siphon, middle cerebral artery, vertebral artery, or basilar artery) confront a 12% per year risk of recurrent stroke in the territory of the stenosis, with the majority of strokes occurring in the first year.1,2 Despite longstanding beliefs that stenoses of some arteries pose different risks than others, WASID showed that patients with disease of the middle cerebral artery were no better or worse off than those with stenosis of another major artery,2,3 so I will address the treatment of all the major intracranial arteries based on the available evidence. Warfarin was not more effective than aspirin in prevention of recurrent stroke and carried a higher risk of serious bleeding and death.4 No subgroup of patients could be identified for whom warfarin was superior to aspirin.3 Prospective, prespecified analysis demonstrated that patients with ≥70% stenosis or recent symptoms, particularly women, faced an enormous risk of recurrent stroke, possibly exceeding 20% in the first year.2 Some clinicians may interpret the WASID results nihilistically, and choose not to investigate the intracranial vessels because patients will just get aspirin as a default medication regardless of the findings. This approach is not advisable, because these patients probably require intensive risk factor modification at a minimum. Others with an eye toward intervention may feel compelled to offer these patients the most aggressive therapy possible, namely intracranial stenting.

The only device available in the US specifically for the treatment of intracranial atherosclerosis is the Wingspan stent made by Boston Scientific. The Wingspan self-expanding stent was studied in 45 patients with symptomatic intracranial (≥50%) stenosis who had recurrent cerebral ischemia on medical therapy. There were no medically treated control patients. The stent was successfully deployed in 44 of 45 patients and the periprocedural (30 day) risk of stroke or death was 4.4% (95% CI: 0.5% to 15%). Restenosis occurred at 6 months in 7.5%, and ipsilateral stroke or death at 1 year occurred in 9.3% (95% CI: 2.6% to 22%; Presented at the American Stroke Association International Stroke Conference, Kissimmee, Florida, February 2006). Other published small stenting registries have shown fairly similar results with devices not available or not approved in the US, but the total number of patients in these studies is only about 100 (including the 45 Wingspan patients).4,5 These data show that the arteries can be widened with reasonable safety, but do not show that this approach is better than medical therapy alone. Nevertheless, the FDA approved the Wingspan device under a humanitarian device exemptions for the indication of “improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease refractory to medical therapy.”6 As clinicians, we want to be able to offer our patients some treatment when all else fails, and this is the purpose of the humanitarian device exemptions. Unfortunately, the term “refractory to medical therapy” is problematic. Analyses from WASID showed that patients who might have been considered refractory because their qualifying transient ischemic attack or stroke occurred while on antiplatelet or anticoagulant therapy were not at greater risk of subsequent stroke than their previously untreated counterparts.2 Thus, even in “refractory” patients for whom stenting seems a logical option, there may be no benefit of this invasive and expensive intervention over medical therapy. Moreover, the confidence interval for risk at 1 year after stenting was extremely broad and could have been greater than 20%, the worst case scenario found in the medically treated WASID population. Ultimately, the stenting registries and the WASID study populations may not be comparable, and it is still anyone’s guess whether one group was actually at greater baseline risk than the other.
Stenting is an experimental procedure, though the FDA has created a loophole for clinical practice. This loophole should remain very small. At present, patients with intracranial stenosis should be treated with antiplatelet therapy. For the high-risk groups, there is great hope and hype about the efficacy of stenting. I share that hope, but a randomized trial of intracranial stenting (coupled with an intensive medical regimen for all) is urgently needed before enthusiasm becomes rampant for an unproven approach that merely fills a therapeutic void.

Disclosures
None.

References
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