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Re: Turk et al and the "How Do We Spin Wingspan?" Commentary

The article by Turk et al[1] is an important contribution to the literature regarding the endovascular management of symptomatic intracranial atherosclerotic disease (ICAD) in general and the use of the Wingspan stent (Boston Scientific, Natick, Mass) in particular. The authors reported restenosis rates from a large prospective registry of 92 patients treated with this device. These rates were much higher than the previously reported small series that lead to the US Food and Drug Administration Humanitarian Device Exemption (HDE) approval.[1-3] Overall rates of restenosis were similar to those in smaller case series with other devices, as noted in the commentary by Kallmes and Cloft.[4] Of note, a particular phenotype—namely young women with supraclinoid carotid stenosis—seemed particularly vulnerable.[2]

We take issue with several points raised in the commentary "How Do We Spin Wingspan?" by Kallmes and Cloft, as well as the cynical tone of this title.[4] First, the "viability" of Wingspan does not depend on these registry follow-up data, as you note in the first paragraph and later in the commentary. The true test of the benefit of this device depends on the outcome of a randomized controlled trial. Second, you suggest that a better conclusion to be drawn from the data is "by avoiding treatment of any lesions with Wingspan, the rates of restenosis might be substantially reduced." That statement is true, of course. Restenosis is not the most important issue, however. An appropriate analogy here is the problem of coil compaction after embolization for aneurysms. By avoiding treatment of aneurysms with coils, retreatment for coil compaction might be substantially reduced. Fortunately, we have data from a randomized controlled trial (the International Symptomatic Aneurysm Trial)[5] demonstrating a significant benefit for coil embolization over surgical ligation for selected patients with ruptured intracranial aneurysms, despite the more frequent need for retreatment in the endovascular group.

Although the asymptomatic restenosis rate with Wingspan may be higher than that reported in the HDE Wingspan study, the rate of stroke associated with restenosis has been relatively low in 2 large postmarketing Wingspan registries.[1,6] This low rate also applies to restenosis following carotid stent placement.[6] The low rates of stroke associated with carotid or intracranial stent placement may be because early restenosis is usually due to neointimal proliferation rather than recurrent atherosclerosis. Neointimal proliferation usually produces a smooth endothelial surface, which is less likely to ulcerate or produce turbulent flow and distal embolization than atherosclerotic stenosis.[7,8]

Ultimately, the effectiveness of Wingspan will have to be determined by a randomized clinical trial rather than carefully performed single-arm registries. We have organized such a trial, which is about to be launched—the Stent Placement versus Aggressive Medical Management for the Prevention of Recurrent stroke in Intracranial Stenosis (SAMMPRIS) trial. This trial will be critical in establishing whether stent placement with the Wingspan system results in a better outcome than medical management in this high-risk cohort. In designing this trial, we carefully examined the data for balloon angioplasty alone, balloon-mounted coronary stents, and the Wingspan stent. The accumulated evidence best supported and continues to support Wingspan over these other options. The Wingspan registries[1,2,6] have been an important prospective source of this data. Procedural complication rates are very low and appear to be lower than those in prior case series with balloon-mounted coronary stents. Additionally, technical success with Wingspan also appears to be superior to the more rigid balloon-mounted system.

In conclusion, the data from SAMMPRIS will be critical in establishing whether stent placement with Wingspan is a beneficial treatment for patients with symptomatic ICAD. If SAMMPRIS fails to demonstrate a benefit, it will provide extremely important data regarding subgroups that show promise for further investigation and benchmarks for technical improvements that may be needed to improve procedural safety and restenosis rates.

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