Response to Letter by Gupta et al

Response:

We thank Dr Gupta and colleagues for their interest in our article. The authors discuss several issues with the content of our recent article.

The first issue was regarding “patient selection.” Our study is a prospective, multicenter, all-inclusive, registry of patients with symptomatic intracranial atherostenoses (>50%) who have undergone treatment with the Wingspan system. Our primary goal was to rapidly gather a large, reliable data set that could be analyzed critically to facilitate a better global understanding of intracranial angioplasty and stenting and to provide an assessment of the role of the Wingspan in the treatment of this disease process. To this end, it was our intention to be as inclusive as possible with respect to the patients enrolled. The inclusion criteria for the current study were not meant to stand as guidelines or recommendations with respect to future patient selection for treatment. This represents a postmarket “real world” registry that provides an accurate assessment of the results, which can be expected with this device when applied by a large and diverse group of operators at selected high volume institutions. Specifically, Dr Gupta et al object to the inclusion of patients who “were not on anticoagulant medication at the time of the qualifying event, if fact, being treated with some type of antithrombotic or antiplatelet therapy” at the time of their qualifying event. Patients in this category were sometimes referred from outside institutions to our centers for the treatment of “medically refractory” symptomatic ICAD. In some cases, the qualifying events had occurred several months before the referral, and the precise medication history at the time of the qualifying event was unreliable. Although it is likely that these patients were, in fact, being treated with some type of antithrombotic or anticoagulant medication at the time of the qualifying event, if the details were unavailable, they were classified as having no “well documented” failure of medical therapy. The authors were further concerned that patients with <70% atherostenoses were included in the registry. Although the WASID subset data certainly demonstrate that patients with <70% stenosis are at a lower risk of subsequent events on medical therapy than those with >70% stenosis, the event rate is still estimated at 11% over 1 year in this group. Furthermore, the Wingspan system has been approved by the FDA for the treatment of symptomatic atherostenoses of >50%. As such, because these patients were being treated at the participating centers, we felt obligated to include these data in the current registry. As more patients are accrued in the registry, we are becoming increasingly able to perform subset analysis on both groups. A specific analysis of the results for patients with >70% stenosis is forthcoming.

The second issue raised was the absence of independent adjudication of clinical outcomes and angiographic results. With respect to the clinical outcomes, a formalized system of independent adjudication for all neurological complications would obviously be optimal in all cases. This point is directly addressed in our “Limitations” section, which states that “Complications...could have been underestimated in the absence of independent neurological adjudication.” At the same time, the vast majority of patients in the current series were followed by a multidisciplinary team composed of noninterventional vascular neurologists, neurosurgeons and neuroradiologists. Given this model it is highly unlikely that any new “clinically relevant” neurological deficits were missed during the periprocedural period. All angiographic images were reviewed by a single interventional neuroradiologist, and the reported stenoses represent the results of these measurements rather than those reported by the individual operators.

Finally, the authors object to our conclusion that the Wingspan system can be applied with an “acceptable” rate of periprocedural morbidity and mortality. The use of the term “acceptable” must be placed in some context—which it very clearly is later in the same paragraph. It was in no way our intention to imply that Wingspan represents the treatment of choice for all patients with this disease process but only that “...the Wingspan system represents a potentially viable option for the endovascular management of symptomatic ICAD in appropriately selected patients”. A second context that must be considered is the relative risk profile of Wingspan in comparison to existing technologies. The 5% to 6% major complication rate reported in our series is analogous to the lowest rates reported for angioplasty alone as well as PTAS with balloon mounted stents. Finally, when the complications are considered individually—one was nondevice-related (contralateral hemispheric infarction) and one occurred in the context of an evolving stroke syndrome—the actual device-related complications were actually quite low. When viewed in an appropriate context, our conclusion that PTAS with Wingspan can be performed with an “acceptable” complication rate seems reasonable.

We thank the authors for their insightful comments in regards to the Multicenter Neuroendovascular Research Collaboration. We continue to enroll new patients into the Wingspan registry and accrue follow-up on all patients who have been treated. These data continue to provide increasing insight into intracranial PTAS and the role of Wingspan for the treatment of this disease process. In addition, we continue to grow our collaboration with the goal of establishing this entity as a powerful mechanism that can be applied to provide the neuroendovascular community with reliable data on new devices and procedures as they are introduced.

Disclosures

None.

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