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***Reply*:**

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Reply:

The premise of the letter by Dr. Levy et al is exactly correct. Everybody has an agenda. We personally think that our agenda is to evaluate scientifically the available data regarding treatment of intracranial atherosclerosis in an effort to improve patient care. We appreciate their attempts to clarify their opinions, but we will stand by the content of our commentary.[1] Our intent was not to personally attack them, but to offer an alternative view of the data that they present and thereby stimulate lively debate. In regard to the use of the term "spin" in the title, we meant no offense. "Spin" is the way in which facts and opinion are presented, and the readers can decide for themselves which presentation they prefer. We do not claim to have a monopoly on truth, but we do believe that we had some valid points that many readers might like to consider, as well as a right to express them.

The debate about appropriate treatment of intracranial stenosis did not start with Warfarin Aspirin Symptomatic Intracranial Disease (WASID) or Wingspan (Wingspan stent; Boston Scientific, Natick, Mass). There was plenty of anxiety among our peers before WASID[2] was published regarding the natural history of intracranial atherosclerosis treated with medical therapy. We recall a fairly static level of anxiety about the natural history and enthusiasm for endovascular therapy during the past decade. The readers can rely on their own memories of recent events and draw their own conclusions.

We admit that we do not know whether restenosis with Wingspan is better or worse than with the balloon-expandable stent or with angioplasty alone, in part because the definition used by Turk et al is new and not directly comparable with previously published results. However, the mathematic bias in the methods used by Turk et al led us to suspect that a higher restenosis rate with Wingspan is a distinct possibility. They could clarify this issue by reporting a binary restenosis rate that includes occlusions. However, only a prospective randomized trial that directly evaluates Wingspan versus another device could really definitively address this issue.

We did not assert that a Humanitarian Device Exemption (HDE) approval for Wingspan was "unnecessary." A HDE approval is indeed necessary for a manufacturer to market a medical device for a specific indication, but by definition, it is based on little scientific evidence. We merely meant to bring attention to some of the scientific uncertainties that surround this HDE-approved device. By their very nature and definition, HDE-approved devices are released for use on the basis of scant data; if there were more data to support their safety and efficacy, the manufacturer would be able to get premarket approval. As Turk et al point out, this HDE status of Wingspan and off-label status of other devices does indeed have potential medicolegal implications, but this issue has nothing to do with the relative efficacy or safety of these devices, which should be the primary consideration.

Drs. Derdeyn and Chimowitz have read cynicism into our commentary, and we can understand this perspective. However, we were really just trying to be blunt in presenting our alternative reading of the data reported by Turk et al. Obviously, on the basis of the article by Turk et al[3] and our accompanying response,[1] a whole spectrum of opinions could be supported by the available data, or lack thereof. This simply demonstrates that there are huge gaps in our knowledge about the best treatment for intracranial stenosis, with many clinically important issues to be sorted out. Prospective randomized studies such as Stent Placement versus Aggressive Medical Management for the Prevention of Recurrent stroke in Intracranial Stenosis (SAMMPRIS) are indeed the way to go, because this is the only way that we will get truly conclusive facts, rather than a few inconclusive facts mixed in with a lot of opinion or "spin."

References

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