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Reply:

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“Mid-term,” “Long-term,” and Other Terms: Making Sense of Clinical Follow-up

The recently published article by Abruzzo et al. describes late mid-term clinical outcomes in patients treated with basilar artery stenting and angioplasty. In the first paragraph of the discussion, the authors note that this is the first description of late-midterm follow up for patients treated with this modality. Yu et al. published their experience with 15 patients treated with basilar artery stenting and followed the patients for a mean of 26 months. This paper should be cited in the current manuscript to detail previous experience with midterm and longer term follow-up.

References


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Reply:

We would like to thank Dr Gupta for taking an interest in our recent publication and welcome his comments because they emphasize the arbitrary nature of what is meant by “long-term” and “midterm.” Although our series was first presented in abstract form at the Annual Meeting of the American Society of Neuroradiology in Vancouver, British Columbia, in May 2002, approximately 2 years before the paper by Yu et al. was submitted for publication to Neurology, it is true that their series was published before ours and should have been cited in our paper.1,2 The final version of our manuscript, which was submitted to the American Journal of Neuroradiology in April 2006, included 3 additional patients (the original abstract reported 7 patients) but did not properly cite Yu et al. for their work. We would like to take this opportunity to respectfully acknowledge those authors. Nevertheless, the real issue, which we consider to be debatable, is what is meant by “long-term follow-up” and “midterm follow-up.” In the discussion section of our recent paper, we indicated that we were reporting “late midterm follow-up” (mean, 31 months) for our cohort, not “long-term” follow-up. We used this expression specifically because in patients with symptomatic intracranial atherosclerosis, we consider “long-term” follow-up to be approximately 4 years.

We believe that in clinical research, the definition of “long-term” follow-up is not only highly subjective but also highly dependent on the pathology, treatment, and patient population. We are not aware of any regulatory document or clinical research manual that provides a standardized definition of “long-term” and “midterm” as they apply to follow-up in clinical research. Although some clinical series have reported a median follow-up of 6.5 years as “midterm,” others have reported a mean follow-up of 10 months as “midterm.” Because these definitions are somewhat arbitrary, we could set the threshold for “late midterm” at 30 months. Using this cutoff, our series would be the first to report a cohort of patients with “late midterm” follow-up after stent placement of symptomatic basilar artery stenosis.

In patients with symptomatic intracranial atherosclerosis, we think that the WASID study properly defines what should be considered “long-term.” In a subgroup analysis of the WASID study data, curves that plot the cumulative risk of ischemic stroke in the territory of the index stenosis against the follow-up period plateau between 3 and 4 years. Consequently, therapies for this condition are primarily aimed at preventing events that occur within a 3- to 4-year window. This would effectively define the threshold for “long-term” follow-up of this condition to be 4 years. Because Yu et al. have reported a series of patients with a mean follow-up of 26.7 months, they have not met our standard of “long-term” follow-up, as indicated in the title of the publication, and as claimed by Dr Gupta. If we define 4 years as “long-term” follow-up, then 2 years could reasonably be considered “midterm.” Extension of this logic suggests that 2 to 4 years would be classified as “late midterm” follow-up. The mean follow-up in our series was 31 months, consistent with the designation “late midterm” follow-up as we have published.

Although follow-up for the series of patients published by Yu et al. was not as long as for our series, it does meet the standard of “late midterm” follow-up according to our new definition. Because this definition has not yet been established as the accepted standard, the first published report of “late midterm” or “long-term” follow-up of stent placement for symptomatic basilar artery stenosis may still be a matter of debate. On this issue, we disagree with Dr Gupta, and we do not believe that there are any errors of content in our manuscript.

References


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