Response to Letter by Kramer et al

Response:

We would like to thank Drs Kramer, Abraham and Jones for their comments with respect to our recently published article.1 We are very interested in their different and so far successful research protocol described in their letter. However, there are a several important points in their letter and their protocol that we feel may benefit from further clarification.

It appears that all the patients treated so far in the Mercy Hospital receive heparin and the GpIIb/IIIa inhibitor (Eptifibatide) during the stenting procedure up to 6 hours before the cardiac procedure being performed, without any use of aspirin or clopidogrel. This appears to be at odds with evidence from the cardiology literature suggesting that any patient with an acute coronary syndrome, or a recent cardiac event, will benefit from aspirin therapy or possibly gain greater benefit from clopidogrel.2 Because these patients are awaiting cardiac bypass, we must assume that these patients have had exposure to at least one or other of these agents before receiving the regime as described. If this is the case then the coadministration of GpIIb/IIIa inhibitors for carotid stenting should be used with caution in light of previous data in carotid stenting.3,4 Data from the trial they describe being performed at their center may help answer some of the safety issues surrounding the use of these agents in carotid stenting, but with small numbers their trial is unlikely to be sufficiently powered to assess safety. We, therefore, urge caution with regard to the statement that their trial uses proper antiplatelet therapy for the stenting procedure because none of the regime they describe has previously been evaluated.

The data presented is indeed encouraging because they have no adverse events to date in their study population. We accept that this is an early stage and not sufficiently powered to change practice, but we must remind ourselves that 0 numerators are not particularly useful, and from the data they have provided the upper confidence interval for this 0 numerator could be as high as 8.1%.5

We have already commented in previous correspondence on the need for a randomized controlled trial, and agree that in the meantime appropriate data entry into carotid stenting registries is an acceptable alternative. This correspondence highlights diversity in worldwide stenting practice, especially in what is considered appropriate antiplatelet therapy for the procedure. Thus, data contained within registries is limited to the extent to which it can be generalized to the population of stented patients. A consensus statement addressing the issues of minimum therapy for all stenting procedures is needed before any further randomized trials are undertaken.

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