Randomized Trial of a Distal Embolic Protection Device During Percutaneous Intervention of Saphenous Vein Aorto-Coronary Bypass Grafts

To the Editor:

We read with great interest the article by Baim et al. The GuardWire distal protection device is the first technique associated with a significant reduction in major adverse cardiac events in patients who receive a stent in a saphenous vein graft (SVG). There is a particularly high reduction of non-Q-wave myocardial infarction (45%) and of no-reflow phenomenon (66%). Interestingly, however, direct stent implantation was performed more often in patients who received the GuardWire (79.4% versus 67.7% in the control patients; P=0.0002).

This difference may influence the results of the study, as recent reports have shown that direct stenting reduces enzyme release and the rate of no-reflow after percutaneous coronary intervention in native arteries, suggesting that direct stent implantation might be an effective strategy to limit the occurrence of distal embolization. Mechanisms involved in effective distal protection devices and direct stenting are not equivalent. The GuardWire has been developed to recover the debris and embolic particles after balloon inflation and stent expansion in SVG. On the other hand, direct stent implantation fixes the plaque immediately and avoids its fragmentation; the stent acts as a scaffold to trap the friable tissue of the plaque before inflation of a balloon. In a recent study (unpublished data, Leborgne, Washington Hospital Center, 2002), we found that direct stenting in the SVG was associated with a 41% reduction of non-Q-wave myocardial infarction as compared with conventionally treated patients. Consequently, a part of the favorable effects of GuardWire might be attributed to the procedure characteristics.

It would be helpful to know whether the protective effect on distal embolization and creatine-phospho-kinase elevation of the GuardWire is maintained if patients are treated without direct stenting.

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Response

The letter by Leborgne et al suggests that some of the benefit observed for distal protection in the Saphenous vein graft Angioplasty Free of Emboli Randomized (SAFER) Trial may have arisen from the slightly greater use of direct stenting (stenting without predilation, 79.4% versus 67.7%) in the GuardWire arm, based on single center registry data showing that successful direct stenting in vein grafts is associated with less periprocedural non-Q-wave myocardial infarction. Unfortunately, such registries may be overly optimistic if other important technical factors (type of stent used, adjunctive pharmacology, etc) are also used, if only patients with successful direct stenting are included, or if selection bias steers patients with more complex lesions away from direct stenting (and toward predilation). These anticipated benefits frequently evaporate when subjected to a prospective randomized trial, as happened for the direct stenting strategy for native vessels.

Still, direct stenting offers some benefits in speed and expense, and operators approached roughly 70% of the saphenous lesions in the 801-patient SAFER trial in this manner. Among patients randomized to stenting without distal embolic protection, 30-day major adverse clinical events (MACE) tended to be somewhat lower with direct stenting versus predilatation (37/262=14.1% versus 26/130=20.0%, P=0.146), although selection bias regarding lesion complexity undoubtedly played a role. Importantly, the use of distal embolic protection offered further benefit for direct stenting, bringing the 30-day MACE down to 16/292=5.5% (P<0.001), and bringing the incidence of no-reflow down (from 11.5% for direct stenting with no embolic protection, to 3.8% with such protection, P<0.001). Finally, an interaction term (interaction of direct stenting with GuardWire protection) was rejected from the multivariable model as a predictor of 30-day MACE.

Given these findings in what is the largest randomized trial of saphenous vein graft stenting to date, we must conclude that 1) the 30-day MACE and no-reflow rates for direct stenting without distal embolic protection remain high; 2) distal embolic protection offers significant benefit even when direct stenting is used; and 3) the slight chance imbalance in the frequency of direct stenting in the SAFER trial did not overestimate the strong underlying treatment effect of distal embolic protection. Lacking a randomized trial that shows that direct stenting without protection is equivalent to direct stenting with such protection, we thus believe the SAFER results stand as strong and compelling evidence favoring the use of distal embolic protection during the stenting of anatomically suitable saphenous vein graft lesions.

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