Distal Embolic Protection for SVG Interventions: Can We Afford Not to Use It?

NORMAN SHAIA, M.D., and RICHARD R. HEUSER, M.D.

From the Phoenix Heart Center, Phoenix, AZ

The development of atherosclerosis in saphenous vein grafts (SVGs) is one of the limiting factors in coronary artery bypass surgery. Approximately one half of vein conduits are significantly diseased or occluded at 10 years. A surgical revascularization strategy is often not pursued secondary to the incremental risks associated with a repeat bypass procedure. For this reason, percutaneous treatment of SVG disease is often the first option for a majority of patients. However, catheter-based treatment of SVG disease is associated with increased morbidity and mortality compared with native coronary arterial percutaneous intervention. This is often the result of distal embolization of atherothrombotic disease, leading to the phenomenon of "no-reflow." Intraprocedural pharmacological therapy has historically been the mainstay of treatment for these patients. However, more recently, the development of a mechanical embolic protection device has shown to be beneficial for the prevention of these complications. This article will review the types of embolic protection devices and the clinical studies that have proven their necessity in percutaneous SVG intervention. (J Interven Cardiol 2005;18:481–484)

Introduction

In the mid-1990s, coronary artery stenting began to emerge as a popular alternative for coronary revascularization. The advent of drug-eluting stents in the past few years has further expanded its utilization for patients with multivessel disease. Prior to the introduction of these modalities for revascularization, coronary artery bypass was the primary means for the treatment of symptomatic coronary artery disease. However, the limiting factor in surgical revascularization is the development of atherosclerosis in saphenous vein grafts (SVGs). Approximately one half of SVGs have been found to be diseased or occluded in serial angiographic follow-up studies at 10 years.[1,2] The Veterans Affairs Cooperative Study demonstrated a 10-year patency rate of 65.8% for SVGs.[2] There are multiple etiologies for the development of SVG disease. After the first year of surgery, the most important contributor of SVG pathology is atherosclerosis with underlying thrombosis. The accumulation of both inflammatory cells and thrombotic material in diseased bypass conduits contribute to the morbidity of SVG intervention. Atherothrombotic embolization is a known consequence with percutaneous treatment of SVG disease. Distal embolization can occur with wire manipulation, balloon inflation, and/or stent deployment. Embolic debris in the distal vascular bed can lead to the phenomenon of "no-reflow." This simply refers to the reduction of antegrade flow in the bypass conduit. No-reflow can result in acute hemodynamic embarrassment as well as intraprocedural myocardial infarction. Studies have demonstrated increased late mortality with creatine kinase-MB elevations after SVG interventions.[3] For these reasons, a variety of technologies have emerged to help minimize distal embolization in these higher risk percutaneous interventions.

Address for reprints: Richard R. Heuser, M.D., Phoenix Heart Center, 500 W. Thomas Road, Suite 900, Phoenix, AZ 85013. Fax: +1-602-234-0058. e-mail: richardheuser@phoenixheartcenter.com

Distal Protection Devices

Over the past few years, a number of embolic protection devices have been developed and introduced into clinical practice. Two basic concepts have emerged in

embolic protection device technology. One is a flow-occlusive balloon that was the first FDA-approved device for SVG intervention. The second is a distal filter that does not occlude antegrade flow. Advantages of a filtering device include continued myocardial perfusion throughout the interventional procedure. However, incomplete occlusion could potentially lead to some embolized material reaching the distal vascular bed. In contrast, balloon occlusive devices theoretically prevent the embolization of all particles. However, the cessation of regional myocardial perfusion may result in hemodynamic instability. This may be problematic in interventions complicated by long procedural times. Although a number of devices have been released to date, the prototypical balloon occlusive device (PercuSurge Guardwire; Medtronics Inc., Minneapolis, MN) and filter wire (EPI FilterWire EX; Boston Scientific, Natick, MA) will be discussed.

PercuSurge Guardwire. The PercuSurge Guardwire embolic protection device consists of a 0.014-inch wire attached to a compliant balloon. This device is advanced across the lesion of interest and inflated prior to initiating balloon angioplasty and/or stenting of the culprit lesion. After each balloon inflation, an export catheter is utilized to collect atherosclerotic and/or thrombotic material, which may have embolized. Early studies demonstrated encouraging results with regard to safety and efficacy of this device. Webb et al.[4] reported the composition and quantity of particulate debris as a result of SVG intervention. As anticipated, light microscopy revealed particulate material consisting of lipid-rich macrophages, fibrin, and cholesterol clefts. The clinical end point of Q wave myocardial infarction was significantly reduced compared to historical controls. It was apparent from these smaller analyses that the PercuSurge Guardwire balloon occlusive device was successful in retrieving atherothrombotic material. A larger, randomized trial was necessary to validate what was observed in these smaller pilot trials. The Saphenous Vein Graft Angioplasty Free of Emboli Randomized trial (SAFER) enrolled over 800 patients to determine the efficacy of the guardwire device.[5] It was the first major, multicenter trial to address the issue of distal protection in SVG intervention. The primary end point was the 30-day composite of death, myocardial infarction, emergency bypass, and target lesion revascularization. The results clearly demonstrated the value of distal embolic protection in preventing the above complications. The reduction in the incidence of no-reflow translated into improved clinical end points. The benefits were apparent in all subsets and independent of the utilization of glycoprotein IIb/IIIa receptor antagonists. This trial was instrumental in providing a strong scientific basis for the necessity of embolic protection.

FilterWire EX. This prototypical filter-based embolic protection device consists of a 0.014-inch guidewire that possesses an oval-shaped filter membrane. The FilterWire EX is delivered through a low profile sheath and deployed 2–3 cm distal to the lesion of interest. The guidewire to which the filter is attached is subsequently utilized for angioplasty and/or stenting. At the conclusion of the procedure, a second catheter is advanced over the filter and the system is removed as one unit (Figs. 1–3).

The Filter Wire during Transluminal Intervention of Saphenous Vein Graft (FIRE) trial was a randomized, multicenter study comparing this filter-based device with the PercuSurge Guardwire system described above.[6] This trial showed similar clinical efficacies of filter protection and balloon occlusion. Major adverse cardiac events occurred in 9.9% of filter wire patients and 11.6% of guardwire patients. This was statistically significant (0.0008) for proving noninferiority of the filter wire embolic protection device.

On the basis of the results of the FIRE trial, filter-based embolic protection devices have become the

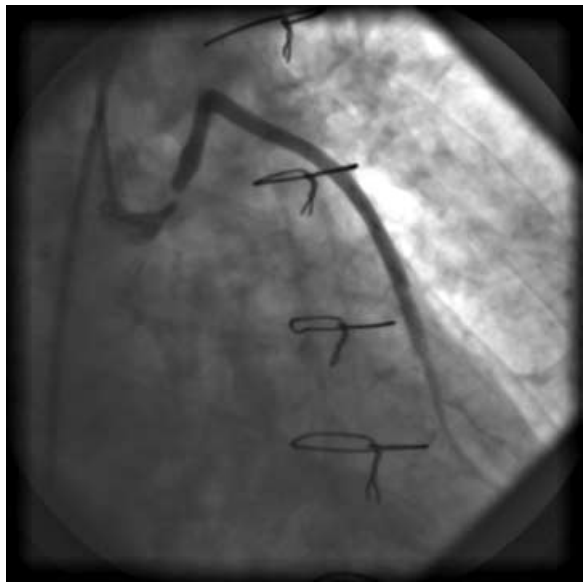

Figure 1. Saphenous vein graft demonstrating a 99% proximal stenosis.

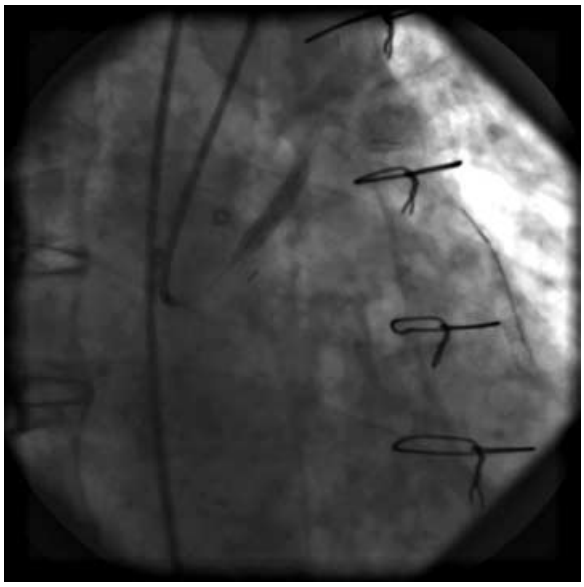

Figure 2. PTCA with distal filter-based embolic protection device.

preferred modality for SVG intervention. However, despite the FIRE trial data, there has been some concern whether filter-based systems can provide complete protection. In the FIRE trial, the nominal pore size of the FilterWire EX device was 110 μm. Since equivalent clinical efficacy was demonstrated in FIRE, it appears that embolized material <110 μm is unimportant clinically. However, Grube et al.[7] reported that $>80\%$ of the particles retrieved with the PercuSurge Angioguard were <96 μm in diameter. This observation conflicts with the notion that filter-based systems offer sufficient embolic protection. A recent analysis by Rogers et al.[8] compared microparticle size retrieved from SVG intervention with both the Angioguard and a filter-based device. The results demonstrated that the vascular filter device was capable of trapping particulate material <100 μm, which was the average distal pore size. Explanations included the possibility that the composite of debris, platelets, and fibrin may reduce the functional pore size of the filter. These microparticle analyses may shed light on the results reported in the FIRE trial. In addition, this data will be instrumental in the development of an optimal embolic protection device for SVG intervention.

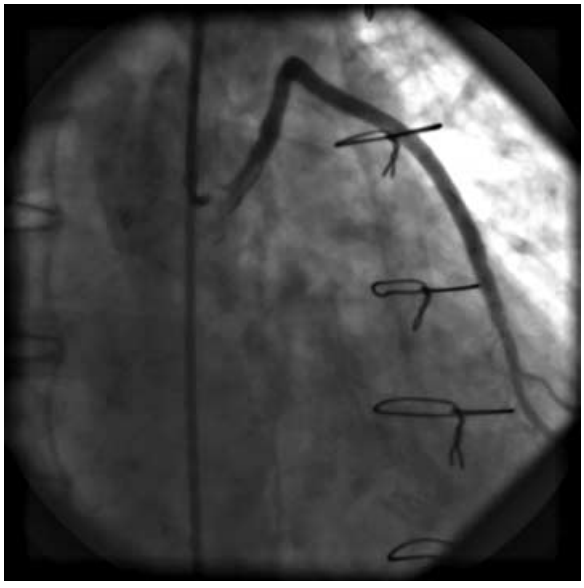

Figure 3. Final angiographic result after retrieval of filter wire.

Conclusion

Despite technological advances in coronary revascularization, percutaneous treatment of SVG disease is still considered a higher risk vascular intervention. Its morbidity and mortality is mainly the result of atherothrombotic embolization into the distal vascular bed. The subsequent development of no-reflow often times lead to intraprocedural myocardial infarction and poor clinical outcomes. Prior to the advent of mechanical devices for this indication, pharmacological therapy for no-reflow was the primary means to treat these patients. The SAFER trial clearly established the necessity for a mechanical embolic protection device for SVG intervention. Its results proved how important distal protection is for minimizing adverse outcomes in SVG revascularization. More recently, filter-based devices have gained popularity with the results observed in the FIRE trial. Vascular filtering devices may offer superiority compared with balloon occlusion devices because of their ease of use and tolerance from a hemodynamic standpoint. Newer generation filter-based embolic protection devices have been released and continue to be tested in clinical studies. Microparticle studies attempt to elucidate the connection between retrieved particulate and the prevention of embolic-related complications. Tremendous advancements have clearly been made in the last few years with SVG intervention. Although "the ideal" embolic

protection device continues to debated, little debate exists over the necessity of embolic protection for SVG intervention.

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