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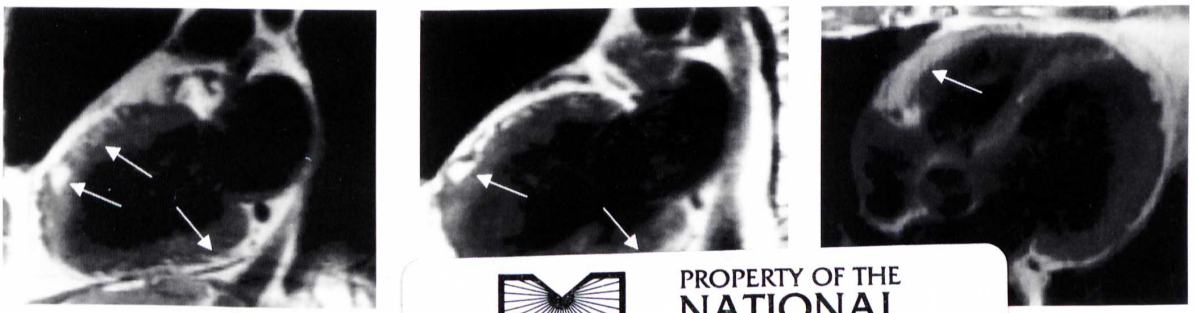

A

st page of the Table of Contents

Circulation
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Volume 105 ■ Number 11
March 19, 2002

Circulation Electronic Pages

Images in Cardiovascular Medicine

Clinician Update

Brief Rapid Communications

Clinical Investigation and Reports*

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Basic Science Reports

Clinical Cardiology: New Frontiers

Images in Cardiovascular Medicine

The cover figure is from the article in this issue by McCrohon et al. Figure 2. T1-weighted turbo spin-echo images before the application of a fat saturation pulse over the region of interest. The arrows point to areas of fatty infiltration of the anterior and inferior myocardium from the epicardial surface. Fatty infiltration is confirmed by the nulling of these areas (black regions) using a fat saturation prepulse in the same plane. The RV free wall shows diffuse high signal consistent with fat (C). See p 1394.

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

Donald S. Baim, MD; Dennis Wahr, MD; Barry George, MD; Martin B. Leon, MD; Joel Greenberg, MD; Donald E. Cutlip, MD; Unsal Kaya, MS; Jeffrey J. Popma, MD; Kalon K.L. Ho, MD, MSc; Richard E. Kuntz, MD, MSc; on behalf of the Saphenous vein graft Angioplasty Free of Emboli Randomized (SAFER) Trial Investigators

Background—Stents provide effective treatment for stenotic saphenous venous aorto-coronary bypass grafts, but their placement carries a 20% incidence of procedure-related complications, which potentially are related to the distal embolization of atherosclerotic debris. We report the first multicenter randomized trial to evaluate use of a distal embolic protection device during stenting of such lesions.

Methods and Results—Of 801 eligible patients, 406 were randomly assigned to stent placement over the shaft of the distal protection device, and 395 were assigned to stent placement over a conventional 0.014-inch angioplasty guidewire (control group). The primary end point—a composite of death, myocardial infarction, emergency bypass, or target lesion revascularization by 30 days—was observed in 65 patients (16.5%) assigned to the control group and 39 patients (9.6%) assigned to the embolic protection device ($P=0.004$). This 42% relative reduction in major adverse cardiac events was driven by myocardial infarction (8.6% versus 14.7%, $P=0.008$) and "no-reflow" phenomenon (3% versus 9%, $P=0.02$). Clinical benefit was seen even when platelet glycoprotein IIb/IIIa receptor blockers were administered (61% of patients), with composite end points occurring in 10.7% of protection device patients versus 19.4% of control patients ($P=0.008$).

Conclusions—Use of this distal protection device during stenting of stenotic venous grafts was associated with a highly significant reduction in major adverse events compared with stenting over a conventional angioplasty guidewire. This demonstrates the importance of distal embolization in causing major adverse cardiac events and the value of embolic protection devices in preventing such complications. **(*Circulation*. 2002;105:1285-1290.)**

Key Words: embolism ■ grafting ■ stenosis ■ angioplasty ■ stents

Catheter-based intervention in saphenous venous aorto-coronary bypass grafts carries a significant (≈20%) risk of a major adverse clinical event (MACE) (predominantly myocardial infarction) or reduced antegrade flow (the no-reflow phenomenon).[1] Several mechanisms have been offered, including spasm of the distal microcirculation, platelet clumping, and most recently, the distal embolization of pieces of friable lipid-rich plaque.[2] Preliminary work with the PercuSurge GuardWire—a device for transient distal balloon occlusion during angioplasty or stent placement that allows recovery of any liberated plaque by aspiration before restoration of antegrade flow—has demonstrated consistent recovery of plaque constituents (cholesterol crystals, foam cells, fibrous plaque) that otherwise would have embolized into the myocardial bed.[3] This initial experience has also suggested a reduced incidence of myocardial infarction (<6%) compared with the 20% historical rate of infarction seen without such distal protection.[4] The Saphenous vein graft Angioplasty Free of Emboli Randomized (SAFER) trial was an 801-patient US multicenter study in which patients undergoing saphenous vein graft intervention were randomized to undergo either stenting with a conventional guidewire or stenting with the GuardWire distal protection device. The SAFER trial was the pivotal trial that led to US Food and Drug Administration approval in August 2001.

Methods

The primary objective of Saphenous vein graft Angioplasty Free of Emboli Randomized (SAFER) trial was to compare the 30-day clinical outcome after saphenous vein graft stenting plus GuardWire

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Dr Leon served as a consultant to PercuSurge Corporation during the trial.

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