Embolic Protection Device for Saphenous Vein Graft Intervention
Too Early to Take Off the Seat Belt

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Saphenous vein graft (SVG) percutaneous coronary intervention (PCI) is considered a high-risk procedure because of the degeneration of the graft, which is associated with a high rate of distal embolization and no-reflow phenomenon. This results in an increased rate of periprocedural myocardial infarction and death.1 As a result, PCI of the native artery is preferred for SVG intervention.2 Prevalence of PCI of a failed SVG is ≈6% of all PCI procedures. SVGs, nevertheless, are still frequently used in bypass surgeries, and given their high failure rate, which averages ≈50% to 60% at 10-year follow-up,3 we are destined to encounter them in future coronary interventions.4

See Article by Brennan et al
Embolic protection devices (EPDs) were introduced to mitigate the distal embolization rate and prevent the no-reflow phenomenon during PCI of the SVG. The US Food and Drug Administration—approved EPD are categorized by mechanism of action: an occlusion balloon followed by aspiration with or without rinsing, or with a filter-based design to capture the plaque debris during the intervention.

The efficacy and use of balloon occluder with aspiration devices (GuardWire) were first studied in the Saphenous vein graft Angioplasty Free of Emboli Randomized (SAFER) trial.5 SAFER was the only randomized trial powered to test the effectiveness of PCI with EPD against PCI alone. The trial demonstrated a reduction in 30-day major adverse cardiac events in the GuardWire-treated patients versus control (9.6% versus 16.5%; P=0.004), mainly driven by reduction in periprocedural myocardial infarction and no-reflow. On the basis of these results, the American College of Cardiology guidelines granted a class I recommendation for EPD use in PCI of failed SVG.6 These guidelines have led to a myriad of devices, including different filters, proximal occluders, a combination of rinse and aspirators—all studied against the GuardWire device or other approved devices, arguing that it is no longer ethical to perform SVG PCI without the use of EPD. Many technologies demonstrated noninferiority versus approved devices and received Food and Drug Administration approval for marketing in the United States—without challenging the findings of the SAFER trial or performing a study with PCI without an EPD control arm.

Yet, despite the level of recommendation, and the improved profile of available marketed devices, the use of EPD for SVG intervention has fallen to as low as 21% in the United States, according to the National Cardiovascular Data Registry.7 As a result, many of the EPD devices are no longer available for marketing, and operators are more selective of the use of EPD versus alternative strategies for the treatment of SVG lesions.

There are numerous reasons to explain the decline in use of EPD devices. First, current devices are still cumbersome and add complexity to the procedure. Second, they are not suitable for every case because of anatomic and profile limitations. Third, the available EPDs are not bullet proof for the prevention of distal embolization and are not free of complications. Fourth, over time, simpler alternative strategies to reduce distal embolization were introduced to the practice, including the use of direct stenting8 and undersizing stents with higher stent/lesion length ratio,9 special stents with a nitinol mesh,10 graft stents, and laser atherec-tomy.11 None of these approaches was studied in a well-designed randomized clinical trial, even though they gained popularity among operators. Finally, there is skepticism and disbelief that the SAFER trial results apply to all SVG lesions, such as in-stent restenosis and proximal or distal anastomosis, and given other limitations of the SAFER trial, the notion is that the study results do not support routine use of EPD for all SVG interventions.

In this issue of Circulation: Cardiovascular Interventions, Brennan et al12 used the National Cardiovascular Data Registry CathPCI Registry to conduct a large retrospective observational study of 49,325 patients with SVG lesions, who were treated with and without EPD between the years 2005 and 2009. Their results corroborate the previously reported underuse of EPD in the United States at only 21%, when one third of the centers did not use EPD at all and only 5.6% used EPD in >50% of SVG PCI. Surprisingly, EPD was not associated with reduced adverse events after 3 years of follow-up. Moreover, there was an increased adjusted risk of no-reflow, dissection and perforation, and periprocedural myocardial infarction in short-term follow-up with the use of EPD.

Although this registry is the largest all-comers cohort studied for the use of EPD for SVG intervention with 3 years of mortality data, the study’s major limitations, as illustrated by the authors, preclude drawing definitive conclusions on the efficacy or the safety of the EPD devices. Among the major
deficiencies of this observational study is the selection bias for the patients who were treated with EPD. These were primarily patients who presented with acute coronary syndrome and patients who had longer lesions, which translated to lesions with higher plaque burden and degenerative score. This and other confounders are difficult to adjust when comparing between the EPD and the non-EPD group. Second, the low quality of the data source from the National Cardiovascular Data Registry CathPCI Registry lacked consistent biomarkers collection, follow-up outcomes on the majority of the patients, and monitoring. Third, the study did not assess plaque morphology, plaque volume, or vein graft degenerative score, which are considered to be correlated with outcome. Finally, the study did not detail the procedural techniques, such as direct stenting, stent undersizing, and the use of pre-emptive vasodilators, that may affect the periprocedural adverse event rates.

Because EPD was used primarily in higher-risk patients, it could be argued that EPD use was beneficial for the high-risk patient population and equates the results to the lower-risk population without EPD use.

Overall, studies examining the debris collected from protection devices have shown a wide incidence of embolization after SVG intervention. There is no doubt that EPD can prevent embolization of plaque debris. Its benefits, however, rely on appropriate patient selection and proper device use—both of which require familiarity and experience with the specific device used to prevent potential complications, such as distal embolization because of misuse of the device, device entrapment, or dissection or perforation of the graft or native coronary.

Like with other interventions, when it comes to SVG intervention, there is no one size that fits all. Selection of the proper treatment based on the clinical presentation and plaque morphology should apply also to SVG intervention, and the selection of EPD should be tailored based on the degree of risk of distal embolization and facilitation of the complexity of the anatomy to use EPD safely. It would be helpful if the decision for using EPD was based on the degree of risk for distal embolization. We suggest 3 levels of recommendations:

1. High: In patients with acute coronary syndrome and thrombus-containing lesions, degenerative graft, including high lipid–containing plaque by optical coherence tomography or near-infrared spectroscopy/intravascular ultrasound.
2. Intermediate: In focal lesion, calcified and torturous anatomy, and borderline landing zone.
3. Low: For proximal and distal anastomosis, fibrotic lesions, and in-stent restenosis.

Alternative strategies to EPD to be considered include direct stenting, stent undersizing, laser atherectomy, and nitinol mesh and covered stents. Intracoronary imaging modalities, such as optical coherence tomography and near-infrared spectroscopy, may be helpful to stratify high-risk morphology with high lipid–containing plaque and can be used as guidance for the need of EPD for SVG intervention. Future study design should take these factors and the heterogeneous nature of the disease into consideration. Finally, operator experience and familiarity with EPD should be addressed by interventional programs, and continued education activities should train operators in appropriate use of these devices.

The use of EPD is analogous to the use of a seat belt, which prevents injury in the event of a car accident. Myths that seat belts were needed only while driving on the highway and not in the city were proven to be wrong. Seat belts, however, can be hazardous in the event of fire. Yet, it is the law to always wear a seat belt while driving. Similarly, with EPD, it is hard to predict when the device will prevent a catastrophic event. Sometimes, PCI to focal lesions can result in no-reflow phenomenon. Until definitive data proves otherwise, it is too early and too risky to take the seat belt off when performing interventions to SVG lesions; therefore, we need to consider routine use of EPD during SVG PCI when appropriate.

Disclosures

Dr Waksman reports personal fees from Biotronik, Medtronic, and Abbott Vascular; grants from The Medicines Company and Edwards Lifesciences; and grants and personal fees from AstraZeneca, Boston Scientific, and Biosensors International. The other author reports no conflicts.

References


KeV Words: Editorials ■ percutaneous coronary intervention
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_Circ Cardiovasc Interv_. 2015;8:
doi: 10.1161/CIRCINTERVENTIONS.115.002371
_Circulation: Cardiovascular Interventions_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7640. Online ISSN: 1941-7632

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