Expanding Use of Embolic Protection Devices

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ABSTRACT

Embolic protection devices were initially developed for the treatment of saphenous vein aorto-coronary bypass graft stenosis due to the significant risk of atheroembolism, and their use is well accepted. The use of these devices for carotid arterial interventions is also well accepted due to the significant consequences of embolization in the cerebral circulation. The use of these devices is extending to other vascular beds to include the renal arteries and lower extremities. We review the basic principles of these devices and their uses in various vascular beds based on our own experience as well as that in the literature.

KEYWORDS: Embolism, grafting, stenosis, angioplasty, stents

Objectives: Upon completion of this article, the reader should (1) understand how distal protection devices work to prevent distal embolization during arterial interventions, as well as potential complications of their use; and (2) identify specific clinical scenarios in which the use of distal protection devices may be appropriate to decrease the risk of distal embolization.

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Catheter-based vascular interventions continue to expand as new technologies make it possible to treat a greater number of disease processes percutaneously. Each generation of devices strives to extend our capabilities and improve the safety of the procedures. It has been recognized that intraprocedural cholesterol atheroembolization is one of the key elements responsible for poor outcomes after endovascular procedures.¹ Embolic protection devices were initially approved to reduce the risk of embolization during stent placement for saphenous vein graft (SVG) stenosis in aorto-coronary bypass grafts. This procedure carries a ~20% risk of a major adverse cardiac event (predominantly myocardial infarction) or reduced antegrade flow (the no-reflow phenomenon).²

Percutaneous treatment of carotid arterial stenosis has also benefited from the development of embolic

protection devices. Transcranial Doppler (TCD) has shown that the majority of patients undergoing carotid artery stent placement experience microembolization.^{3,4} At the time this article was written, there were three manufacturers in the United States with systems approved by the Food and Drug Administration (FDA) for carotid stenting that include a distal protection device. Several more devices have obtained a “conformité européenne” (CE) marking and are available in Europe. Several trials support the efficacy of these devices in improving the safety of carotid stenting.⁵⁻⁷

EMBOLIC PROTECTION DEVICES

Embolic protection devices can be divided into two general classes: those that temporarily stop blood flow

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Figure 1 Medtronic PercuSurge GuardWire (Medtronic Corporation, Minneapolis, MN).

by occluding the vessel and those that maintain blood flow. The first category consists of a guidewire with an occlusion balloon at the distal end. The concept of distal protection with balloon occlusion was created by Jacques Theron and later adopted for commercial use by several companies.⁸ The PercuSurge GuardWire (Medtronic, Minneapolis, MN) utilizes distal occlusion, which temporarily blocks the flow of blood while the intervention is performed. Any debris trapped in a stagnant column of blood can be aspirated before the occlusion balloon is deflated (Fig. 1). Advantages include the capture and aspiration of a majority of particles, many of which are small (< 250 microns). Disadvantages of distal protection with occluding balloons include the complete occlusion of flow making it difficult to see the lesion, the possible formation of thrombus distal to the balloon due to the low flow state, and the potential for allowing embolic debris along the edge of the balloon to go downstream once the balloon is deflated or vessel expansion occurs due to dilation from angioplasty or stenting.

A different approach is to place a filter basket on the end of the guidewire to capture embolic debris while maintaining flow. There are several companies with various models and delivery mechanisms. Cordis ANGIOGUARD (Miami Lakes, FL), RX AccUNET Embolic Protection, Guidant Abbott Vascular (Santa Clara, CA), and Boston Scientific EPI Filterwire EX/EZ (Natick, MA) have been used extensively in the carotid and coronary vascular beds with excellent results (Figs. 2A–E). These devices represent the type of design where the filter is fixed on the end of the wire. Other

devices include mobile filters where the lesion is crossed with standard or modified guidewire, and the filter is then delivered on the guidewire and deployed for use; these include the Guidant Abbott Vascular Emboshield (Redwood City, CA) and the EV3 SpideRX Filter (Plymouth, MN). Advantages of filter systems include the continuity of flow. Disadvantages include the passage of small particles, capture efficiency and complications related to advancement, deployment and recovery of the filters.

EMBOLIC PROTECTION IN CLINICAL PRACTICE

The concept of trapping debris released during angioplasty and stenting of arterial lesions is appealing, especially if there are clinical implications from emboli that result from angioplasty and stenting. TCD monitoring during carotid angioplasty and stenting has demonstrated that despite use of embolic protection devices, there continues to be microscopic embolization. The clinical significance of these emboli may depend on the vascular bed and size of the emboli. We have found embolic protection devices useful in clinical practice.

SUPERFICIAL FEMORAL ARTERY

There has been a natural progression in the use of distal embolic protection in percutaneous intervention of saphenous vein aorto-coronary bypass grafts and carotid arteries to other vessels including the renal arteries and now the lower extremities. In an ischemic limb, down-

stream embolization into the peripheral arterial vasculature jeopardizes the microcirculation and can result in persistent or progressive ischemia. There have been few published reports on distal embolization in angioplasty and stent placement; several series report a rate of 1.6 to 2.6%^{9,10} including aortoiliac interventions. However, Matchett et al reported 4 of 16 patients who developed significant distal embolization in a high-risk group of patients with blue toes.¹¹ Distal embolization during thrombolytic therapy in limb-threatening ischemia is higher. Published studies have reported rates of 3.8 to 37% depending on the risk group¹²⁻¹⁴

We have found the use of distal protection beneficial in femoropopliteal interventions in three instances: mechanical atherectomy, catheter-directed thrombolysis in acute limb ischemia, and when adjunctive treatment

with thrombectomy catheters is performed for acute limb ischemia.^{14,15} We also strongly consider use of distal protection in recanalization and standard intervention (angioplasty and stent placement) in certain high-risk patients with limited runoff.

In mechanical atherectomy, we found in an early series of 10 patients with femoropopliteal disease 100% capture of particles and debris.¹⁴ In one case, a no-flow phenomenon was observed after the atherectomy was performed; flow was promptly restored after removal of the filter basket, which was full of debris; there was no thrombus within the filter. Debris consisted of cut atherectomy plaque pieces, ranging in size from 0.5-mm to 10-mm lengths, similar in appearance to the pieces retrieved from the atherectomy chamber (Figs. 3A,B).

Figure 2 (A) Guidant Abbott Vascular Emboshield (Redwood City, CA). (B) EV3 SpiderRX Filter (Plymouth, MN). (C) Boston Scientific EPI Filterwire EZ (Natick, MA). (D) RX AccUNET Embolic Protection, Guidant Abbott Vascular (Santa Clara, CA). (E) Cordis ANGIOGUARD Capture Guidewire, Cordis Endovascular (Miami Lakes, FL).

A **B**

Figure 3 (A) High-grade superficial femoral artery lesion treated successfully with mechanical atherectomy device. (B) EPI Filterwire EZ with captured plaque fragment dislodged from the atherectomy device.

The technique of use of distal protection is simple. The filter basket is advanced past the lesion and deployed. Appropriate anticoagulation is administered. After the intervention is performed, the filter and its contents are removed. For total occlusions, filters that can be advanced over or after a conventional wire are preferred. An alternative method is to cross the total occlusion with a Glidewire and a 4F glide catheter (Terumo, Tokyo, Japan), and exchange the 0.035-inch Glidewire for the EV3 Spider Filter system (Plymouth, MN). Key features to remember with the use of any distal embolic filter during superficial femoral artery intervention are the following: Do not let the filter migrate and become meshed with any of the stents, size the filter to the vessel, and do not let the basket become too full.

Another use for distal protection is catheter-directed thrombolytic therapy for acute limb ischemia. We have used embolic filters to treat thrombotic arterial occlusions in cases in which we have crossed lesions requiring angioplasty or mechanical intervention. We

have also used protection after overnight thrombolytic cases that require further intervention but still have residual clot and/or plaque in the target vessel (Fig. 4). Several series have described distal embolization during thrombolytic therapy between 3.8 and 37%.^{12,13,15} Distal embolization occurs in almost all thrombolysis cases but only becomes apparent as a procedure-related complication in a small subset due to incomplete lysis of fibrin-enriched thrombus or due to plaque that becomes dislodged; again, high-risk patients cannot tolerate such hits to limited runoff vessels.

A third area for the distal protection in peripheral interventions includes the use of adjunctive treatment with thrombectomy catheters (Fig. 5A–C) such as Possis Medical (Minneapolis, MN) or the Rinspiration system (Kerberos Proximal Solutions Inc., Cupertino, CA). As Kasirajan et al found, particulate embolization accounted for 12% of the initial thrombus volume with 99.83% < 100 μ m and none > 1000 μ m.¹⁶

Finally, the largest application in femoropopliteal distal protection includes standard intervention

Figure 4 (A) Acute ischemia with occlusion of stent in the right superficial femoral artery. Patient underwent 22 hours of thrombolytic therapy overnight with residual plaque/debris seen along in stent. (B) Distal balloon protection was provided with the use of the PercuSurge (Medtronic, Minneapolis, MN) allowing safe angioplasty and subsequent stent placement to treat the lesions.

including angioplasty and stent placement of high-grade and totally occluded arteries. Discovery of visible embolic debris in standard femoropopliteal interventions with filters varies from 66 to 100%.^{14,17,18} We found the differences in particles captured between standard intervention and those from mechanical atherectomy to be in size and content (Fig. 6A–C). Siablis et al found the macroscopic particulate debris, which were extracted from all the filters (17 of 17) contained fresh thrombus, calcified minerals, cholesterol, and fibrin; the mean diameter of the largest particle per specimen was 1702 (range, 373 to 4680 microns).¹⁷ It is not economically justifiable to use protection in all standard interventions for it is still an off-label use in the United States. Likewise, careful stent deployment may minimize the risk of plaque embolization. However, for patients with threat-

ened limbs with compromised runoff or with lesions that appear suspicious, distal protection should be considered.

RENAL ARTERY

Despite the acceptance of endovascular treatment of renovascular hypertension and ischemic nephropathy, the clinical response to revascularization is difficult to predict, and it can even deteriorate despite a technically successful procedure.¹⁹ The feasibility and safety of embolic protection devices during renal artery stenting has been studied.^{20–22} In our practice, we have used the Filterwire EZ (Boston Scientific, Natick, MA) selectively (Fig. 7A,B). Currently, we reserve use of embolic protection devices to those patients with symptomatic renal artery stenosis in a solitary kidney. There is a need

Figure 5 (A) Patient with acute occlusion of the left axillary-brachial artery reconstituting flow ~15 cm distal. (B) Occlusion was crossed with 0.035-inch guidewire followed by the EV3 Spider advanced over a 0.014-inch BMW (Abbott Guidant, Santa Clara, CA). (C) After aspiration via ThrombCat (Kensey Nash Corporation, Exton, PA) and subsequent angioplasty, angiogram shows improved flow; patient then underwent overnight infusion of thrombolytic therapy that cleared the remaining clot.

Figure 6 (A) An EPI Filterwire EZ was placed past an irregular lesion in the femoropopliteal bypass graft prior to angioplasty. (B) Visible debris in the EPI Filterwire EZ. (C) Macroscopic analysis of the debris shows calcified plaque fragments. (Courtesy of Vibha Bhashin, M.D., Department of Pathology, UTHSCSA, San Antonio, TX.)

for prospective studies to determine which patients will benefit from use of embolic protection devices.

Several anatomical differences make the use of embolic protection devices in the renal artery more technically challenging. These have been previously

discussed.¹⁹ Briefly, the renal artery usually originates at a right angle to the aorta. If this occurs in the internal carotid artery, it is possible to anchor the guide catheter/sheath with a wire in the external carotid artery; this is not possible in the aorta and therefore the system is less

Figure 7 (A) A 68-year-old woman with hypertensive crisis (systolic 300) who developed acute renal failure when blood pressure lowered to 200 mm systolic (creatinine 5.1; blood urea nitrogen 129). Patient found to have bilateral renal artery stenosis. (B) EPI Filterwire EZ (Boston Scientific, Natick, MA) was deployed in the right renal artery post stent placement. Both kidneys were treated. Creatinine was 1.3 at 20-month follow-up. (Images courtesy of R. Stefan Kiesz, M.D.)

stable. The ostial nature of renal atherosclerotic vascular disease and decreased stability compound the technical difficulty of the passage of the filter system, often requiring predilation and/or a buddy wire.

The embolic protection devices are designed for use in longer, narrower vessels without bifurcations. There can be poor wall apposition due to the relative size of the embolic protection devices with respect to the renal artery as well as incomplete protection of the entire renal vascular bed, due to early bifurcation of the renal artery. The current filter designs are lacking when it comes to treating the renal arteries.

SUBCLAVIAN ARTERY

Treatment of subclavian artery stenosis is typically reserved for patients with clinical symptoms of subclavian steal. Patients with left internal mammary artery (LIMA) coronary bypass grafts can develop progressive subclavian artery stenosis, putting the patient at risk for coronary ischemia due to insufficient flow or even potentially develop a coronary steal phenomenon through the bypass graft requiring treatment.²³ Patients on dialysis may also develop symptomatic subclavian stenosis that can benefit from endovascular treatment.^{24,25}

In our practice we are seeing a subset of patients with left subclavian artery stenosis who are not symptomatic but have coronary artery disease requiring coronary artery bypass grafting (CABG). Because of the risk or disease progression in the subclavian artery, our current practice is to treat patients who are scheduled for CABG with a LIMA bypass and a hemodynamically significant

subclavian artery stenosis preoperatively; at the time the decision is made to perform bypass. In some of these cases, there is antegrade flow in the vertebral artery. One method to promote flow reversal in the vertebral artery in such instances is induction of hyperemia in the extremity by inflating a blood pressure cuff to a supra-systolic level for several minutes and then releasing the cuff as the subclavian stent is deployed. More recently, in patients with large vertebral arteries with antegrade flow, we have deployed the Filterwire in the vertebral artery

Figure 8 EPI Filterwire EZ deployed in left vertebral artery during subclavian artery stenting in a patient scheduled for coronary artery bypass graft with a left internal mammary artery bypass graft.

prior to subclavian artery stenting to decrease the risk of embolization to the posterior cerebral circulation. This has been reported by others as well²⁶ (Fig. 8).

VERTEBRAL ARTERY

Approximately a quarter of strokes involve the posterior circulation.²⁷ The vertebral artery origin is the most common location for vertebral artery stenosis. In the New England Medical Center Posterior Circulation Registry, 20% of patients with vertebrobasilar symptoms had a proximal vertebral artery lesions. Fifty-two percent of these patients had a stenosis of the contralateral vertebral.²⁸ The risk of stroke after transient ischemic attack varies between 25% and 29% during 5- to 6-year follow-up.²⁹ Despite medical therapy with warfarin or aspirin, these patients have a recurrent rate of stroke or death of 16 to 18%.³⁰

Vertebral artery stenting is accepted as a treatment for patients with vertebral artery stenosis who have failed medical therapy. As with the carotid arteries, there is clinical concern of stroke from embolization during vertebral artery stenting, which has prompted clinicians to explore the use of embolic protection devices during vertebral artery stenting.³¹

CONCLUSION

Embolic protection devices have increased the safety of SVG interventions as well as carotid arterial interventions. Their use is being explored in other vascular territories. The currently available devices are not always optimal for the vascular beds in which they are being used. Prospective trials with embolic protection devices designed for specific vascular beds will need to be completed to determine which patients will benefit from their use before widespread use of these devices is indicated.

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