

Embololic Protection in Femoropopliteal Artery Intervention

What devices are available and when is it necessary?

BY HANK J. FREEMAN, MD, AND JOHN H. RUNDBACK, MD

Femoropopliteal occlusive disease is a major contributor to claudication and critical limb ischemia and is present in 20% to 40% of patients with peripheral arterial disease (PAD). As the population ages and technology advances, the number of endovascular treatments performed for femoropopliteal lesions is expected to increase. Endovascular recanalization and treatment of the superficial femoral artery (SFA) is complicated by significant peripheral emboli in up to 5% of cases,^{1,2} in part due to the large plaque burden and high rate of long-segment occlusions frequently encountered in this vascular distribution. In addition, certain interventions, such as extirpative atherectomy, mechanical thrombectomy, thrombolysis, and stent graft implantation, may be associated with a higher risk of embolic complications (Table 1), which may have devastating sequelae in patients with compromised tibial runoff (Figure 1).

The use of distal embolic protection devices (EPDs) has improved outcomes in patients undergoing treatment for coronary, carotid, and renal vascular disease.³⁻⁵ However, the use of EPDs for femoral and popliteal disease has received less attention. This article discusses the clinical utility of protected SFA and popliteal interventions.

TECHNICAL CONSIDERATIONS FOR FEMOROPOPLITEAL USE

There are numerous distinct considerations when using EPDs during femoropopliteal revascularization. Because the femoropopliteal artery is a tapering vessel, it is critical to have a wide range of potential protection diameters. Devices deployed in the popliteal artery or tibioperoneal trunk rarely need to exceed 3 mm to 4 mm in diameter,

whereas EPDs used higher in the SFA will require larger diameters. Arterial ectasia may render the use of any available EPDs impossible.

The femoral arteries often have a large plaque burden, and there is a high frequency of chronic total occlusions (CTOs). Most EPDs have limited torqueability, and primary lesion passage for eccentric and complex stenoses may be difficult. As in other vascular distributions, the use of steerable "buddy" wires may facilitate successful advancement of the EPD. However, in CTOs, there is insufficient support for any of the EPD wires to allow successful primary use. In these cases, recanalization must be accomplished using other catheter-wire-device systems, with secondary EPD placement prior to definitive revascularization. Only two of the available EPDs can thus be used for CTOs. The GuardWire (Medtronic, Inc., Santa Rosa, CA) has a .038-inch outer diameter, but can be passed through a 4-F or 5-F Glide catheter (Terumo Medical Systems, Somerset, NJ) or equivalent .038-inch lumen catheter that has traversed the lesion. The

TABLE 1. HIGH-EMBOLIC-RISK FEMOROPOPLITEAL INTERVENTIONS

- Thrombolytic therapy
- Mechanical thrombectomy
- Extirpative atherectomy (plaque excision)
- Stent graft insertion
- Friable atheroma
- Unstable plaque

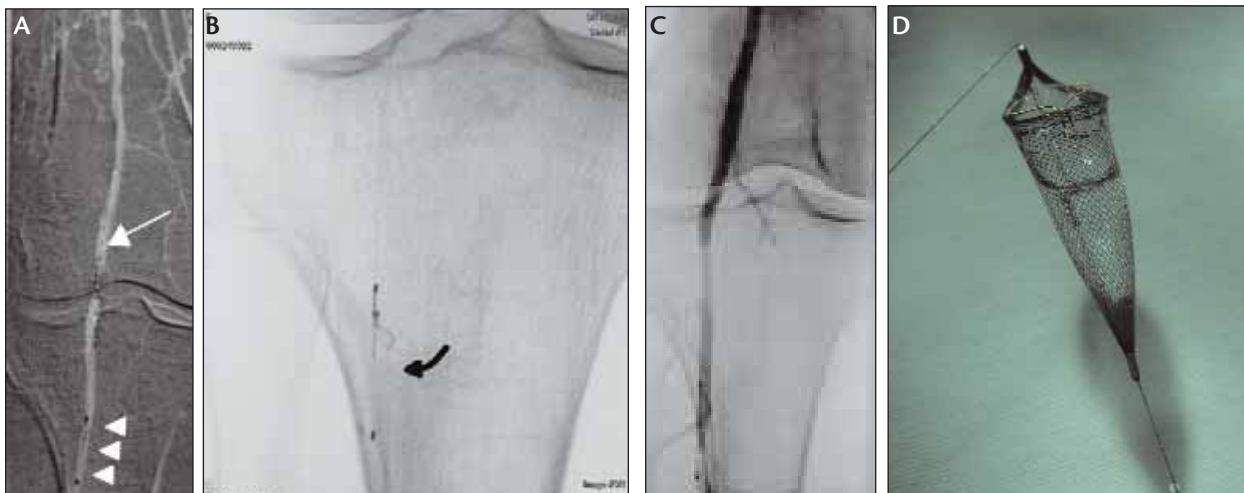


Figure 1. High-grade, midpopliteal stenosis with the cryoplasty balloon (arrow). A SpiderRX EPD is seen in the distal popliteal artery (arrowheads) (A). Magnified fluoroscopic image shows the fully deployed SpiderRX EPD in the lower popliteal artery (curved arrow) (B). The popliteal artery after cryoplasty. There is an excellent result without residual luminal narrowing. No spasm is seen at the EPD site. The SpiderRX device was subsequently captured and retrieved (C). The SpiderRX EPD after the procedure showing debris within the filter basket (D).

SpiderRX system (ev3, Plymouth, MN) can be advanced over any .014-inch wire using a unique dual-lumen monorail construction; once the 3-F SpiderRX introducer catheter is positioned beyond the lesion, the crossing .014-inch wire is removed, and the filter is deployed for subsequent over-the-wire intervention.

In patients with compromised tibial outflow, macroembolization of plaque poses a greater theoretical clinical risk than microembolization of cholesterol crystals. Because the aspiration catheters provided with the GuardWire and TriActiv FX (Kensey Nash, Exton, PA) balloons have a limited ability to extract larger fragments of embolized material, most interventionists prefer using filter devices within the femoropopliteal arteries, if anatomically feasible.

TYPES OF EPDs

There are two general types of EPDs available: filter-based devices and balloon-occlusion devices (Table 2). All EPDs available in the US are marketed for either saphenous vein coronary artery bypass grafts or carotid indications. It is noteworthy that the use of any EPDs in the SFA and popliteal artery not only represents an off-label use, but is also an anatomic bed for which these devices were not specifically engineered.

Balloon-based devices, including the GuardWire and TriActiv FX systems, provide complete arterial occlusion. Despite the fact that the balloons are volume mediated rather than pressure inflated, these systems have the advantage of providing secure wire positioning due to vessel wall

apposition, which may facilitate over-the-wire passage of .035-inch lumen stent platforms. Because these devices are of the wall-contact type, there is also the potential advantage of achieving a better seal than filter-based devices. The GuardWire should be prepared and inflated after crossing the lesion, which is different than described in the instructions for use. Preparing the balloon *in situ* helps to maintain a low balloon profile to facilitate lesion crossing. By triple inflating the balloon, occlusive diameters of up to 6.3 mm can be achieved. The TriActiv FX balloon occlusion device provides an easier inflation mechanism, but is limited to a maximum diameter of 5 mm. There is also a tendency toward spontaneous, gradual deflation after 15 to 20 minutes of use. With either balloon occlusion EPD, postprocedure aspiration is performed before the occlusion balloon is deflated to remove any embolic debris.

Filter-based devices are more widely used by interventionists; they work by deploying a windsock-shaped filter and guidewire distal to the lesion. The filter contains microscopic pores (approximately 100 μm in diameter) that maintain blood flow, but trap emboli. The filters should be appropriately sized to the vessel in question. The obvious benefit to these devices is that blood flow is maintained; the negatives are that sometimes there is an incomplete seal, and there is a risk of movement within the vessel that can induce spasm.

DISCUSSION

The use of embolic protection is the standard of care in both carotid artery interventions and saphenous vein



Figure 2. Distal protection during in-stent femoral atherectomy and cryoplasty. Arteriogram shows severe in-stent restenosis within the femoropopliteal segment (A). Use of the SilverHawk atherectomy device (FoxHollow Technologies, Redwood City, CA) with embolic protection (B). Completion arteriogram shows wide patency of the stenotic segment and good distal runoff (C, D). Debris within the basket of the FilterWire EPD is similar to debris collected in the atherectomy device chamber (E, F).

bypass graft interventions because of the inherent high risks involved in the procedures. The literature is not as clear concerning femoropopliteal interventions, although embolic protection may be an important adjunct in high-risk patients.

High-risk patients encompass those with limited distal runoff, a history of thromboembolic disease, aneurysmal disease, and high-risk endovascular procedures, including

lytic therapy with or without mechanical thrombectomy and atherectomy. Microemboli occur in all peripheral arterial interventions in varying degrees; however, patients with compromised runoff have less capability to withstand such complications. Other high-risk patients include those with vulnerable or unstable plaque. There is limited research in the coronary and peripheral vascular literature regarding what constitutes a vulnerable or unstable plaque, although future research using cross-sectional imaging may allow a preprocedural assessment of plaque morphology relevant to treatment planning.

Embolization rates after thrombolytic therapy and mechanical thrombectomy range from 3.8%⁶ to 37%.⁷ Embolic protection allows for a more aggressive approach to acute arterial occlusions. This synergistic technique could theoretically shorten the lytic therapy time and decrease both bleeding and embolic complications.

Atherectomy devices may pose a unique risk of embolization. In a study by Wholey et al, embolic protection was studied with the use of the SilverHawk atherectomy device. Debris was retrieved in the filter device in all cases in this small, single-center trial. The debris was histologically studied and was shown to consist 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 SilverHawk chamber.” In our own experience, embolization has also been observed with the SilverHawk device (Figure 2). Although plaque embolization may be related to imperfect technique and inadvertent overfilling of the capture chamber, the use of embolic protection during atherectomy should be highly considered as an important adjunct.⁸

Siablis et al evaluated the use of filter-type EPDs during 16 procedures for femoral occlusion, including five patients with acute thrombosis treated with rheolytic thrombectomy.

Macroscopic debris was captured in all cases, and consisted of fresh thrombus in the acute cases

and calcification with fibrin and cholesterol crystals in the more chronic cases. The average diameter of the largest captured material was 1.7 mm, suggesting that macroembolization was the prevailing risk in these patients.⁹

Another study by Konig et al evaluated embolic protection for femoropopliteal angioplasty procedures. Markedly reduced flow suggesting filter clotting was more prominent in patients with concentric lesions rather than calcified or

TABLE 2. EPDs AVAILABLE FOR FEMOROPOPLITEAL USE*

Name	Manufacturer	EPD Type	Comments
FilterWire	Boston Scientific	Filter	Maximum diameter 5.5 mm
AccUNET	Abbott	Filter	Approved OUS for carotids
SpideRX	ev3	Filter	May use in CTOs; introduce over any .014-in wire; diameters up to 8 mm
Angioguard	Cordis	Filter	Maximum diameter 7 mm
Interceptor	Medtronic	Filter	In US carotid trials
TriActiv FX	Kensey Nash	Balloon	Maximum diameter 5 mm; loses inflation after 20 min
GuardWire	Medtronic	Balloon	May use in CTOs; maximum diameter approximately 6.2 mm

* Use of EPDs in the lower extremities represents an off-label application.

occluded lesions. Distal macroembolization after filter removal (angiographically visible) was detected in five of five patients with concentric lesions, but in no patients with calcified or occluded lesions. This finding surprised the authors who thought the smooth, concentric lesions were signs of uncomplicated lesions. One explanation is that the filter itself may have caused periprocedural thrombus due to obstruction of the device. Therefore, this study concluded that embolic protection should not be routinely used in femoropopliteal angioplasty.¹⁰

“Embolic protection may be useful in high-risk patients . . . and high-risk procedures . . .”

There are additional negative considerations concerning the use of embolic protection. The use of the device may increase the time and complexity of the procedure, which can lead to complications. Cost is another factor, as the devices range in price from approximately \$800 to \$1,000. Finally, device-specific adverse events may occur, although these have not been described in early experience. Notably, all devices may theoretically damage the endothelium at the site of deployment, possibly resulting in late stenoses, endothelial injury, and disease progression or thrombosis.

SUMMARY

The current role of embolic protection during femoropopliteal intervention is not clearly established. Data suggest that embolic protection should be strongly considered in high-risk patients (limited distal runoff, vulnerable or

unstable plaque, aneurysmal disease) and high-risk procedures (after thrombolytic therapy, atherectomy). However, there is insufficient evidence to recommend the routine use of this technology. More research is needed concerning embolic protection in the peripheral arterial vasculature prior to advocating routine use of this technique. ■

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