Embolic Protection Questions Answered

What is the embolic risk for endovascular SFA intervention?
When is embolic protection necessary?

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Embolic debris created in interventions involving carotid artery stent placement, as well as in interventions in treating saphenous vein aortocoronary bypass grafts stenosis, has been well accepted.[1-6] It is a natural progression to assume that other vascular beds, such as the lower extremities, experience the same deleterious effects from thromboemboli created in interventional procedures.

Is embolic debris an issue in interventions involving the femoropopliteal arteries? Yes, all embolic debris can be harmful to patients—especially those who have compromised distal runoff, which is the the majority of patients treated for peripheral vascular disease.

Which interventional procedures create embolic debris in the lower extremities? In our limited experience, all interventional procedures have the potential to create embolic debris. The plaque burden in the femoropopliteal sector and bypass grafts can be eccentric, ulcerated, and composed of calcific and soft tissue plaques—all of these lesions can be affected by disruption and embolize downstream.

FEMOROPOPLITEAL ANGIOPLASTY AND STENT PLACEMENT

The incidence of embolic debris following routine angioplasty and stent placement can vary from 1.6% to 25%, depending on the series (Table 1).[7-10] There has never been a trial or registry using embolic debris as a primary endpoint. In the series by Matchett et al, a cohort of 80 patients with threatened limbs received stent placement. Of this group, 19% (15) developed blue toes, and four of those 19 patients incurred amputations.[10] It is still difficult to know whether the embolization was the deciding factor in causing these patients to lose a limb.

Figure 1. Femoropopliteal bypass graft with lesions seen with a filter basket distal to the areas that were subsequently angioplastied with a 5-mm PTA balloon catheter.

In early articles studying a small number of patients in whom a distal protection filter was used during superficial femoral artery (SFA)/popliteal interventions, the rate of visual embolic debris following the procedure was high, ranging from 63% to 100% (Figures 1-3).[11,12] Siablis et al recently used the SpiderFX filter (ev3 Inc., Plymouth, MN) in a series of 17 patients with acute and subacute limbs; macroscopic particulate debris was extracted from all the filters (17 out of 17) containing fresh thrombus, calcification minerals, cholesterol, and fibrin. The mean diameter of the largest particle per specimen was 1,702 µm (range, 373 µm to 4,680 µm).[13]

An excellent study was performed recently by Karnabitidis and colleagues using distal protection filters in 48 patients with lower-extremity disease.[14] They found particles with a major axis >1 and >3 mm in 58% (29) and 12% (6), respectively, of the examined filters.[14] Collected particles consisted primarily of platelets and fibrin conglomerates, trapped erythrocytes, inflammatory cells, and extracellular matrix.[14] Increased lesion length, increased reference vessel diameter, acute thromboses, and total occlusions were positively correlated with higher amounts of captured particles ($P<.05$).[14]

ACUTE LIMB ISCHEMIA

A second area of intervention concerns the management of acute limb ischemia using thrombolytic therapy and mechanical thrombectomy devices (Table 2). From a series of interventionists, the rate of embolization from thrombolytic therapy varies from 3.8% to

37%.[15-17] With rheolytic thrombectomy devices, the rate of embolization can vary from 25% to 56%, depending on the series.[18,19]

MECHANICAL THROMBECTOMY CATHETERS

There has been much controversy regarding the use of mechanical thrombectomy devices to treat peripheral vascular disease. In an early article, we found the pieces seen in the filter, ranging in length from .5 mm to 10 mm, were significant enough to potentially cause occlusions of the tibial vessels, which only have diameters of 1 mm to 3 mm.[20,21] This may be particularly relevant in patients with single-vessel runoff. Such patients already face a serious risk, and, should an abrupt occlusion with an embolic plaque occur, medical therapy would not reopen these vessels. With an abrupt occlusion of the distal anterior, posterior tibial, or pedal dorsalis artery, the only recourse would then be to recanalize these occluded distal vessels emergently. Smaller debris may possibly not cause such occlusions but may result in occlusions of more distal branches that may be difficult to detect on completion angiograms. Hence, with femoropopliteal intervention, such as with the SilverHawk device (FoxHollow Technologies, Redwood City, CA), distal showering of cut plaque particles will occur. We believe the significance of the showering varies depending on the patient's underlying runoff status as well as the dispersion of emboli. Other studies have also shown a high incidence of embolic debris after mechanical thrombectomy; Mewissen found visible trapped debris in the 58% of his 21 patients who had femoropopliteal atherectomy procedures.[22]

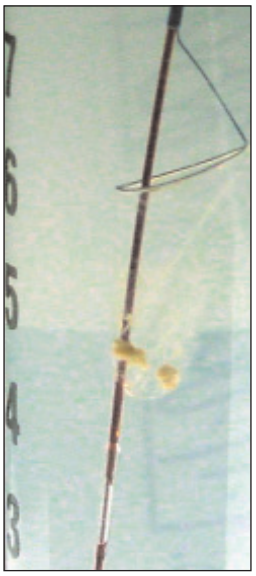

Figure 2. Embolic debris captured in EPI EX filter basket.

TABLE 1. EMBOLIZATION DURING PTA AND STENT PLACEMENT OF AORTOILIAC/SFA

Author	Patients	Embolized	Consequences
Lin[7]	493	8 (1.6%)	Surgical revision
Dyet[8]	43	1 (2.3%)	Surgical revision
Uher[9]	76	2 (2.6%)	Surgical revision
Matchett[10]	80	15 (19%, blue toe)	4 amputations

TABLE 2. DISTAL EMBOLIZATION DURING THROMBOLYTIC THERAPY IN LIMB-THREATENING ISCHEMIA

Author	Patients	Embolized	Consequences
Rickard[15]	37	11 (37%)	Failed lysis
Chalmers[16]	72	6 (8.3%)	Thrombectomy
Wholey[17]	237	9 (3.8%)	2 amputations

METHOD OF USE

There are several types of filters and occlusion devices that can be used in the femoropopliteal system. The size of the common femoral artery can vary from 3 mm to 6 mm, the femoropopliteal artery can vary from 2 mm to 5 mm, and the infrapopliteal region can vary from 1 mm to 3 mm. Hence, some of the vessels are too small for most distal protection filters.

Occlusive balloon-based devices, including the GuardWire (Medtonic, Inc., Minneapolis, MN) and TriActiv FX system (Kensey Nash Corporation, Exton, PA), provide complete arterial occlusion.[23] Advantages include achieving a better seal than filter-based devices; however, disadvantages include total occlusion with loss of lesion location, in addition to potential thrombus formation distal to the balloon. The device is carefully negotiated through the stenosis or occlusion and then inflated once in position. The maximum diameter is 5 mm to 6.3 mm, depending on the device used.[23] With either balloon occlusion embolic protection device, postprocedure aspiration is performed to remove any embolic debris before the occlusion balloon is deflated (Figure 4).

Filter-based devices, which are more widely used by interventionists, work by deploying a windsock-shaped filter and guidewire distal to the lesion.[23] The filter contains micro-

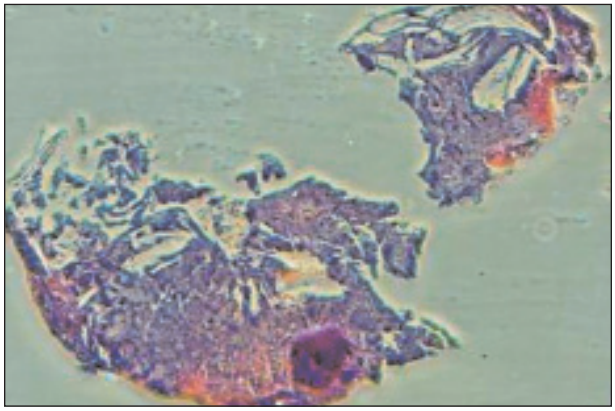

Figure 3. Gross microscopic debris from the filter revealing a mixture of cholesterol crystals, calcified plaque, and cells.

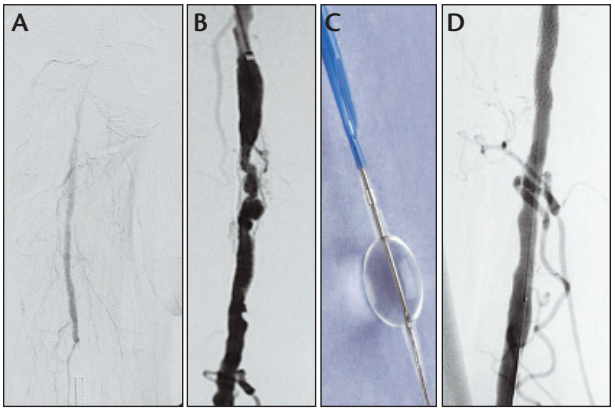

Figure 4. Initial angiogram showed occlusion just cephalad to a previously placed SFA stent. Popliteal reconstitutes distally with one-vessel runoff (A). Lesion after 22 hours of thrombolytic therapy. There is still residual thrombus or plaque that is not lysing (B). Illustration of the PercuSurge device (Medtronic) (C). With the PercuSurge balloon deflated, final angiogram taken after additional stent placement. Visible debris was retrieved during aspiration (D).

scopic pores (approximately 100 µm in diameter) that maintain blood flow but trap emboli.[23] The filters should be appropriately sized to the vessel. The obvious benefit to these devices is that blood flow is maintained; unfortunately, sometimes there is an incomplete seal and a risk of movement within the vessel that can induce spasm.[23] There is also a real risk of pulling the filter too far back, causing it to become lodged on the stent struts.

The easiest of the filters to use are those that can go over coaxial wires that are deployed first. With the ev3 SpiderFX and the Emboshield (Abbott Vascular, Santa Clara, CA), you can pass the .014-inch to .019-inch guidewires past the high-grade lesions and occlusions, followed by the filter. Other filters either deploy concentrically along the wire, such as the Angioguard (Cordis Endovascular, a Johnson & Johnson company, Warren, NJ) or the Accunet (Abbott), or eccentrically, such as the Boston Scientific EPI (Natick, MA) (Figure 5). Some open-mouth filters can also be used to try to retrieve dislodged embolic debris in the lower legs after other interventions (Figure 6).

ECONOMIC ISSUES

Today in the US, filter use in the lower extremities is considered off-label and is not reimbursed. As a result, their extensive use is restricted, especially when considering the total costs of the other devices: balloon catheters ($200), self-expandable nitinol stents ($1,000), and mechanical thrombectomy catheters ($2,500). As a result, the filter, which costs more than $1,000, will bring the cost of equipment alone to more than $6,000 for extensive procedures.

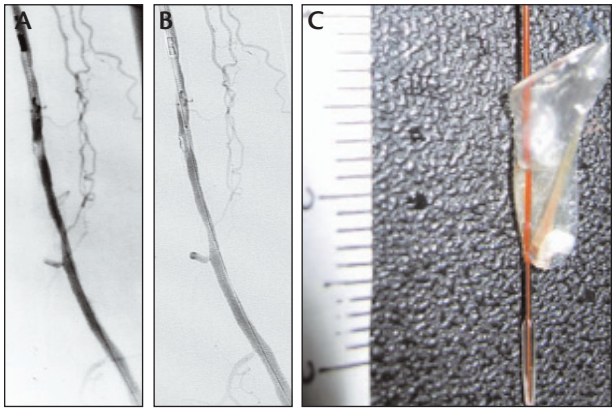

Figure 5. Calcified and soft tissue plaque in the right SFA near the adductor canal (A). SilverHawk delivered to the lesion, and several passes were made with good angiographic results (B). Gross visualization of the debris within the basket (C).

In the current regulatory and outcomes-driven market, it will probably require a randomized trial to justify the increased use of filters in lower-extremity interventions, despite the obvious benefits that they provide.

CONCLUSION

In arterial intervention cases, when there is a risk of dis-

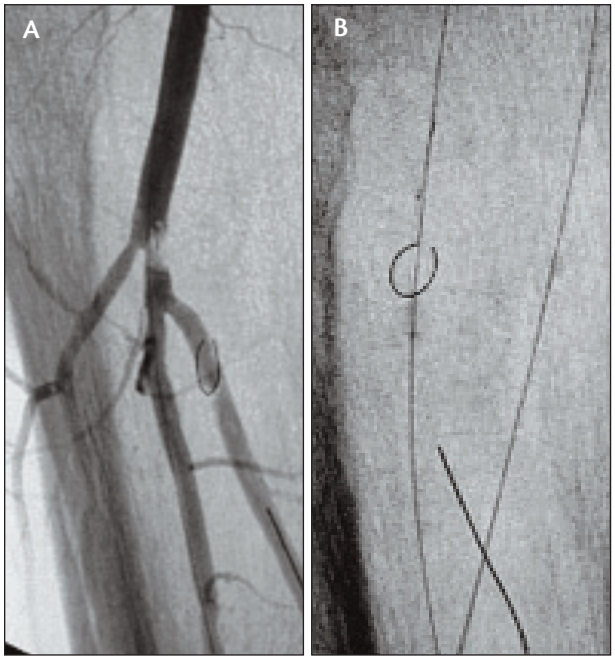

Figure 6. Case of a dislodged plaque following mechanical thrombectomy of the mid-SFA. Debris can be seen lodged in the tibioperoneal trunk (A). A distal protection device was used to try to remove it. We were able to capture the free fragment, but it was too large to retrieve through the ipsilateral sheath (B).

lodged fragments breaking free, the use of distal embolic protection has been important in preventing these fragments from occluding key vessels downstream. This has been proven in studies of the saphenous vein coronary bypass graft and carotid stenting. It is no different in the lower extremities, whether performing simple angioplasty and stent placement, mopping up after thrombolytic therapy, or using mechanical thrombectomy catheters.

Technologically, the current filters are useable, although redesigning the filters to accommodate the lower extremities would be beneficial. Economically, it is impossible to use filters in all cases. We recommend using filters in all mechanical thrombectomy cases, if possible. We recommend using filters in standard intervention in cases with very limited runoff and with lesions that appear complex and vulnerable to fragment. ■

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