Embolization in Lower Extremity Percutaneous Interventions: Recommendations and Strategies for Embolic Filter Protection Use

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Abstract

Embolization following percutaneous intervention is a universal problem occurring in all vascular beds, including the periphery. Embolic filter protection (EFP) is effective in capturing macrodebris following percutaneous peripheral interventions (PPI). Predictors of distal lower extremity embolization appear to be a recent onset of symptoms in patients with total or subtotal occlusion, long, irregular and calcified lesions, degenerative grafts, intraluminal filling defects, and the use of the Silverhawk atherectomy device and mechanical thrombectomy. Filters have their own set of potential problems, and filter retrieval is probably one of the key steps where problems are likely to occur. In this manuscript, we discuss embolization in the lower extremity following PPI, and provide tips on how to avoid problems with embolic filter protection use.

Embolization following percutaneous intervention is a universal phenomenon that has been reported in various vascular beds, including the carotids,1 renals,2 saphenous vein grafts,3 and the lower extremities.4–8 Treatment of embolization varies with different vascular beds, but range from an attempt to suction the macrodebris using a 6 Fr or 7 Fr multipurpose guiding catheter and/or specialized catheters such as the Export (Medtronic, Minneapolis, Minnesota) or QuickCat Extraction catheter (Kensey Nash, Exton, Pennsylvania) to trapping and retrieving these emboli with filter baskets and snares. Interventionalists have also attempted treating vessels with macroembolic debris with angioplasty and stenting, excimer laser, rheolytic thrombectomy, thrombolysis, and surgical interventions. Furthermore, glycoprotein (GP) IIb/IIIa inhibitors have been used in treating patients with embolization and slow flow. Irrespective of how macroembolization is treated, it is likely to result in a longer procedure time, larger radiation exposure to both operator and patient, and the use of more contrast dye. The outcome of patients with macroembolization is also variable, ranging from a benign course to serious outcomes, such as stroke, myocardial infarction, renal failure, and amputation, depending on the treated vascular bed.

In this review, we argue that preventing macroembolization in the lower extremities during PPI is a necessary approach when treating high-risk lesions or with the use of certain devices to minimize immediate and long-term complications.

In our experience, the use of embolic filter protection (EFP) appears to be justified in patients with the following high-risk lesions and therapies:
1) recent symptoms of claudication or limb ischemia and with totally or subtotally occluded vessels, including both *de novo* or recently stented vessels;9–11
2) undergoing rheolytic thrombectomy with or without thrombolysis;4,5,10
3) treated with the Silverhawk atherectomy device;7
4) In high-risk lesions8 that are moderately or severely calcified, long and irregular, or in the presence of intravascular filling defect;
5) degenerative bypass grafts;
6) severely diseased or limited distal runoff (Figure 1);
7) known prior embolization during PPI.

Thrombus is highly prevalent in patients with recent symptoms (< 6 months) and occluded or subtotally occluded vessels. In preliminary data presented at New Cardiovascular Horizons 2007 from the Dethrombosis Registry,11 intravascular ultrasound (IVUS) on patients with recent symptoms (< 6 months) and occlusions prior to and after treatment with the power pulse spray (P-PS) technique revealed the presence of definite thrombus in 16/17 patients (94%) studied (Figure 2). Definite thrombus was present angiographically in only 2/17 patients (11.8%). The prevalence of thrombus angiographically was largely underestimated in these patients with recent symptoms and occluded/subtotally occluded vessels. Treating these vessels using the combination of rheolytic thrombectomy and thrombolysis was partially effective in dissolving thrombus and led to...
distal macroembolization in 3/17 patients (17.6%) that required further extended therapy with no subsequent amputation or death.10

Thrombotic lesions are more likely to embolize, particularly with mechanical thrombectomy. In a review by Kasirajan et al,4 patients with acute limb ischemia treated with Angiojet thrombectomy experienced an embolization rate of 2.3–9.8%. In 235 patients (30% acute, 5% subacute and 59% chronic > 3 months) treated with thrombolysis alone, Wholey et al5 demonstrated that embolization occurs in 3.8% of these patients with 2 subsequent amputations. As noted in the dethrombosis registry,10 combining the two modalities of thrombolysis (using P-PS) and mechanical thrombectomy appears to have a higher embolic rate compared to historic reports on either modality alone,4,5 likely as a result of loosening the thrombus with thrombolysis without totally dissolving it and a subsequent higher dislodgement rate with mechanical manipulation.

In patients treated with mechanical thrombectomy, the use of an embolic filter protection device might be beneficial in reducing occlusive macroembolization. Recent data from Siablis et al6 showed in 16 patients with acute (treated with the angiojet) and subacute (treated with PTA and stenting) thrombosis using the TRAP (Microvena, Plymouth, Minnesota) or SPIDER (ev3, Plymouth, Minnesota) filter, macrodebris were captured in 17/17 (100%) of baskets deployed during treatment mostly consisting of fresh thrombus, calcium, cholesterol and fibrin. In their series, procedural success was 100%.

Silverhawk atherectomy (Foxhollow, California) is an effective tool in treating lower extremity peripheral obstructive disease.12 In our experience and others, we have noted that the use of the Silverhawk device, however, is associated with a significant embolization rate, mostly consistent of atherothrombotic, and shaving debris not trapped by the nosecone of the atherectomy cutter (Figure 3). Suri et al7 reported on 10 cases of Silverhawk atherectomy with distal embolic protection and showed that macroembolization occurred in 100% of these cases when treating superficial and popliteal arteries.

The use of angioplasty and/or stenting in high-risk lesions also leads to frequent macroembolizations. Karnabatidis et al6 reported their experience in a prospective registry of 48 patients undergoing standard endovascular procedures on lesions > 75% in severity and a mean length 52.2 mm. Fifty vessels were treated using nitinol filter baskets. In their series, procedural success was 98.3%, with one case of distal embolization. In 2 other cases, distal spasm and a side branch occlusion occurred respectively. Particles > 1 mm and > 3 mm were retrieved in 58% and 12% of their cases and consisted of atheromatous plaque and thrombus. Declotting mechanical procedures were strong independent predictors of embolization. Also, in a univariate analysis, lesion length and diameter, acute thrombus, and total occlusions correlated with a higher embolization rate.

The Embolic Filter Protection in Preventing Lower Extremity Distal Embolization (PROTECT) registry is currently evaluating the EFP ability in capturing macrodebris in the lower extremities and preventing visible
embolization, slow flow and loss of a distal tibial runoff. Patients are included if they had moderate of higher calcification of any length, total occlusions of any length, presence of an intravascular filling defect, irregular appearing lesions over 30 mm in length or any lesion over 50 mm in length. Preliminary data on 28 patients treated with EFP in this registry revealed 16/28 patients (57%) experienced macroemobolization caught in the filter. Patients undergoing Silverhawk atherectomy had a 100% embolization rate (9 out of 9 patients), 78% of it was deemed clinically significant by the operator (> 2 mm debris in its longest axis). Patients undergoing angioplasty with stenting experienced a 31% embolization rate (5 out of 16 patients), 25% of which was deemed clinically significant. Embolization was seen in 45% of patients with de novo lesions and 5 of 7 (71.4%) of restenotic lesions (4/5 treated with Silverhawk atherectomy and 1/5 was a totally occluded vessel treated with PTA and stent). Also, total occlusions embolized 50% of the time versus 61.1% in non-total occlusions. The PROTECT registry is still ongoing and final analysis of predictors of embolization will be reported separately. So far no distal embolization or problems in retrieving the SPI-DR (ev3) or Emboshield (Abbott Vascular, Redwood City, California) filters have been reported.

There are several potential problems with the current off label use of EFP, and the endovascular specialist needs to be aware of them. Many of these problems are extrapolated from other vascular beds, but could potentially occur in lower extremity PPI:

1) Filters might be difficult to retrieve because they can get stuck on stents or balloons; the filter wire can break off; or a filled filter with debris might not be fully captured back into its retrieval catheter. Filter retrieval is probably the most likely problem to be encountered by the interventionalist;
2) Filter can fill up with macrodebris with migration of debris to side branches (Figure 4); interruption of distal flow; and lack of ability to retrieve the filter;
3) Spasm and trauma to the vessel wall can occur where the filter is parked;
4) Rupture of filters can lead to a large amount of macrodebris released at once with generally worse distal embolization and slow flow;
5) Lesions have to be crossed before the filter can be deployed and embolization can occur in this first step, though less likely to be significant in a lower extremity vascular bed given the low profile of current filters;
6) Filters will not capture microdebris (less than 120 microns). These generally tend to be important in the carotid and renals, but their clinical significance in the lower vascular bed in unclear at this time.

Below we present some tips on how to avoid problems with the use of EFP in the periphery. We have typically used these guidelines with minimal to no complications encountered using EFP:

1) We use a 7 or 8 Fr sheath to allow with relative ease the removal of a partially captured filter when this is encountered. I personally prefer the sheath with a removable hemostatic valve such as the Pinnacle Destination Guiding Sheath with Cross-Cut valve option (Terumo, Somerset, New Jersey). As illustrated in Figure 5, a partially captured filter might not cross the hemostatic valve, but can still be easily retrieved with the hemostatic valve unscrewed from the sheath. After emptying the filter, this can then be easily retrieved back into its retrieval catheter and pulled out successfully thru the hemostatic valve. This offers the advantage of keeping the sheath in and completing the procedure as necessary;
2) A long contralateral sheath might be advised, allowing a partially retrieved filter to travel through the sheath when it is pulled out. This avoids a partially retrieved filter from getting stuck on stent struts or calcified plaque during retrieval;
3) Do not oversize the filter;
4) Choose a filter that you can deploy over a 0.014-inch wire that has already crossed the lesion. Currently, in our laboratory, we use the SPI-DR (ev3) or Emboshield (Abbott Vascular) filter;
5) We leave approximately 2 inches from the distal tip of the balloon or stent to where the filter is parked in the vessel. This avoids inadvertent balloon or stent strut getting stuck on the filter;
6) If Silverhawk atherectomy is used, the filter needs to be parked far enough distally to account for the forward motion of the nosecone during cutting. An ideal parking point for the filter would be 1 to 2 inches beyond the length of the nosecone estimated from the distal edge of the lesion (Figure 6);
7) Never pull hard on an entangled filter, as the filter can rupture or filter wire can break;
8) Predictable anticoagulation needs to be considered. In our laboratory, we elect to use bivalirudin instead of heparin in the majority of our patients because of its predictable anticoagulation response and its
safer profile than heparin as demonstrated in PCI. However, no randomized data between bivalirudin and heparin currently exist in the periphery, and therefore, heparin, a less expensive anticoagulant, remains a widely utilized anticoagulant during PPI. In addition to bivalirudin, we use GP IIb/IIIa receptors in patients with thrombotic lesions or lesions with slow distal flow.

9. On occasion, a buddy wire is left adjacent to the deployed filter in cases of balloon angioplasty alone. If the filter appears to be filling fast, then it is retrieved and a new filter is placed over the buddy wire. This buddy wire needs to be removed, however, in case of atherectomy or stenting.

In summary, embolization is a universal phenomenon in percutaneous intervention, and lower extremity angioplasty is no exception. Predictors of embolization have not been clearly defined in the lower extremity, but early observational data suggest that recent total or subtotal occlusions, long irregular and calcified lesions, and degenerative grafts are high-risk lesions for embolization. The use of certain devices is also associated with more frequent embolization, such as the Silverhawk atherectomy catheter and mechanical thrombectomy, with and without thrombolysis. The off-label use of EFP in the periphery is increasing as the understanding and consequences of embolization have become more apparent to the endovascular specialist.

Filter protection is effective in retrieving macrodebris that appears large enough to be clinically significant. It is unclear whether microdebris has consequences in the lower extremity, as the latter might be a more tolerant vascular bed when compared to the heart, carotids, and renals. EFP use is not without risks, and device retrieval is the likely step where problems might be encountered. Also, EFP use in the periphery is currently not reimbursed by insurance carriers, which might be a hindrance to its use in certain hospital systems.

Multicenter prospective registry or randomized trials are needed at this time to define the ultimate cost-effectiveness and safety of EFP in the periphery before routine wide applications can be recommended. Endpoints to be examined need to include radiation exposure to the patient, contrast use, length of hospital stay, renal failure, blood transfusion, distal atheroembolism and slow flow, amputation, death, myocardial infarction, unplanned emergency surgery, and conversion of claudication to critical limb ischemia.

References