

Distal Embolization in Femoropopliteal Interventions

An overview on how to handle this complication and—better yet—how to prevent it with the use of embolic protection devices.

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Distal embolization (DE) occurs frequently during femoropopliteal (FP) interventions. Treatment of FP atherosclerotic lesions with balloon angioplasty, stenting, atherectomy, embolectomy, or catheter-directed lysis is likely to yield significant debris.¹⁻¹¹ Despite a high rate of DE reaching 100% in some reports,^{3,10} data suggest that only 2% to 3% of patients will eventually require additional pharmacological and/or mechanical treatment.¹²

PREDICTING DE

There are several angiographic predictors of DE, including total occlusions; long, irregular, and calcified lesions; and thrombotic occlusions.^{6,12,13} Also, patients treated with atherectomy or mechanical thrombectomy are likely to experience significant DE.^{1,2,6-11,14} The Embolic Filter Protection in Preventing Lower Extremity Distal Embolization (PROTECT) registry showed that DE occurs in all types of FP interventions, with the highest rate occurring with directional atherectomy.¹⁰ In this registry, macrodebris (≥ 2 mm in diameter) occurred in 27.6% of patients treated with angioplasty and stenting and in 90.9% of patients treated with SilverHawk atherectomy (Covidien).

TREATING DE

Treating DE consists of manual suction with the use of multipurpose guiding catheters or specialized aspiration catheters, the use of forced suction with continuous pump aspiration (Indigo system, Penumbra, Inc.), or the use of Venturi effect aspiration (AngioJet system, Boston Scientific Corporation). Filter baskets and snares have also been used to remove embolic debris. When aspiration and trapping of debris fail, treatment has been attempted with

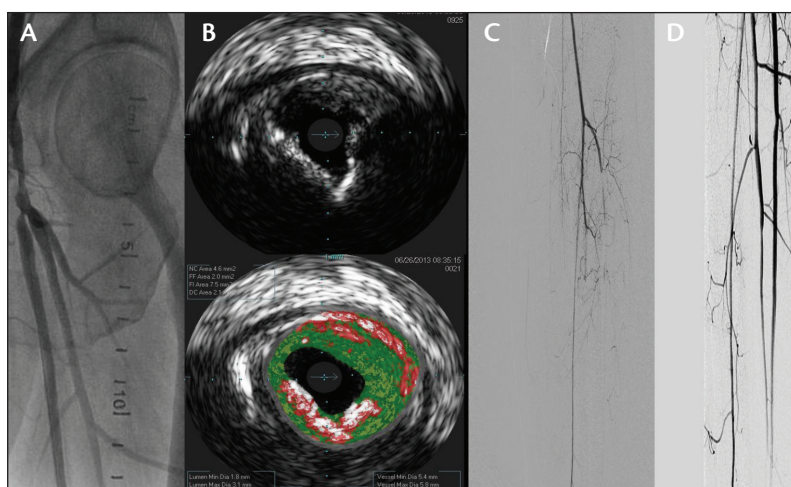


Figure 1. Left common femoral artery and ostial superficial femoral artery (A) calcified lesions (B) treated with atherectomy and no embolic filter protection. DE in tibial vessels (C) was seen and was successfully treated with laser atherectomy (D).

angioplasty and stenting, excimer laser (Spectranetics Corporation) ablation (Figure 1), catheter-directed fibrinolysis, glycoprotein IIb/IIIa inhibitors, or power-pulse spray using the AngioJet system.

PREVENTING DE

The best approach to avoid DE is to prevent its occurrence. The Food and Drug Administration (FDA) has approved the SpiderFX filter (Covidien) and the Proteus embolic capture balloon (Angioslide Ltd.) for embolic debris capture during FP interventions. The SpiderFX Filter was specifically approved in calcified FP lesions during treatment with TurboHawk or SilverHawk directional atherectomy (Covidien). The Nav6 Embolic Protection system (Abbott Vascular) is not approved by the FDA for FP embolic protection. However, we often use this filter off-label because of its independent wire motion from the basket, preventing filter movement during FP treatment. We find this particularly useful with the use of Jetstream atherectomy (Boston Scientific Corporation) (Figure 2) when applied in high-risk lesions.

To our knowledge, there is no epidemiological data to illustrate the trend in using embolic protection in FP intervention. Also cost-effectiveness data are not available. It remains unclear whether reducing length of hospital stay or procedural time will offset the cost of embolic protection devices. In our laboratory, the use of these embolic protection devices has been limited to high-risk lesions and devices for DE. Several reports indicated that DE can be treated with no subsequent serious outcomes and questioned the need for routine use of embolic protection devices during FP interventions.^{15,16} Cost and potential complications from using embolic protection were cited as the most common reasons to avoid the use of these devices on a routine basis. The random use of embolic protection in FP interventions is not warranted and should be reserved to lesions, procedures, and patients who are at high risk for DE with anticipated detrimental consequences. A randomized trial of embolic protection versus no protection in high-risk patients is warranted.

WHEN DE DOES OCCUR

DE is associated with amputations.^{1,11} DE also appears to increase procedure time leading to more radiation and contrast exposure to the patient¹⁷ and prolongs the length of hospital stay.¹⁸ Embolic protection devices have been very effective in capturing debris, including

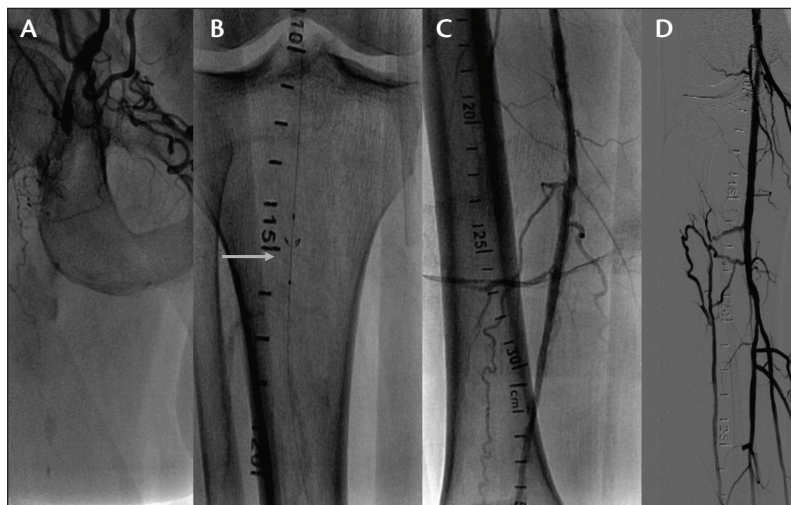


Figure 2. Calcified long total occlusion of the right distal common femoral artery and right superficial artery (A) treated with Jetstream atherectomy using a Nav6 filter (white arrow, B) with good results (C) and no distal embolization (D).

large debris that are considered likely to be clinically significant. Siablis et al³ showed that the use of embolic filters in thrombotic lesions were able to safely capture debris in 100% of baskets with 100% clinical success. Our group demonstrated that embolic filters in acute and subacute thrombotic lesions treated with excimer laser prevented embolization of macrodebris in 85.7% of cases treated in conjunction with an embolic filter protection.⁷ In another study,⁸ macrodebris > 2 mm were present in 50% of patients with thrombotic occlusions treated by thrombolysis using the ClearWay transcatheter balloon irrigation (Maquet, Cardiac Assist) captured with the use of embolic filter protection.

Embolic Protection

The use of embolic filters or the Proteus embolic capture balloon¹⁹ is well within the expertise of an endovascular specialist and typically adds little time or risk to the procedure. The DEFINITIVE Ca++ study,⁶ a multicenter, prospective registry, demonstrated the safety of the SpiderFX distal embolic protection device in moderate to severe calcified FP disease in conjunction with the TurboHawk or SilverHawk devices. This study was the basis for the approval of the filter by the FDA to use in FP interventions while performing directional atherectomy in moderate to severe calcified lesions. In this registry, the filter prevented DE in 97.5% (119/122) of cases where debris was captured in the filter. Furthermore, patients who are high risk of developing acute limb ischemia from DE such as those with single-vessel runoff or severely diseased runoffs may

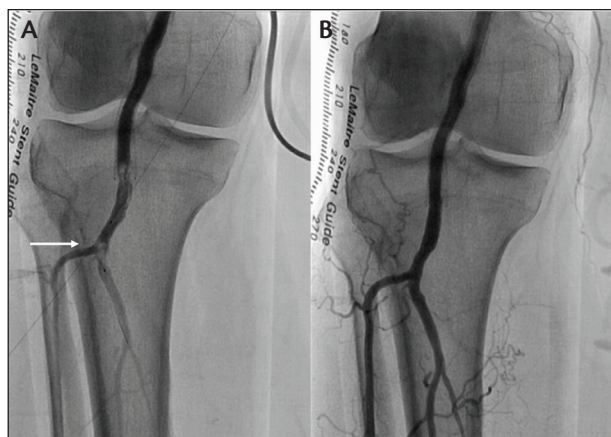


Figure 3. In-stent stenotic-thrombotic lesions treated with laser atherectomy and adjunctive balloon angioplasty under SpiderFX filter protection deployed with the opening of the basket just above the bifurcation of the anterior tibials (white arrow, A). Basket is filled with debris with slow flow distally (B). After basket removal (B), flow is back to normal.

potentially benefit from embolic protection. Finally, there is considerable debate about whether embolic filters are needed in patients with FP chronic total occlusion (CTO) treated with a subintimal approach.²⁰ DE requiring further treatment has been reported in 1.2% to 3% of CTO patients.^{21,22} In contrast, Spiliopoulos et al²⁰ reported no significant visible DE in CTO patients treated with a subintimal approach. In this study, however, 60% of these lesions were Transatlantic Intersociety Consensus (TASC) A and B that generally have a low potential for DE.

Although technically easy to learn, embolic filters may carry inherent risk. Filters can get stuck on stents when retrieved, overfill with debris, or create spasm and dissection at the site of deployment. We find that these complications can be avoided by deploying the filter at a safe distance (2 inches away from stented segments or far enough from the nosecone of a SilverHawk device), using a sheath with a detachable hemostatic valve (we use the Pinnacle Destination sheath, Terumo Interventional Systems), avoiding oversizing the filter to the blood vessel, and using intravascular nitroglycerin as needed to treat spasm.

CONCLUSION

DE occurs frequently during FP interventions. The real value of embolic protection is likely to be in high-risk lesions for DE, such as thrombotic lesions (Figure 3), total occlusions, and long irregular calcified lesions. Patients who are likely to benefit from the use of embolic protection are those with single-vessel runoff or severely dis-

eased runoffs. A low threshold to use a filter with atherectomy has been adopted in our laboratory, particularly in long lesions and recent occlusions. Attention to technique in deploying and retrieving these filters is needed to reduce complication rates. The use of the Proteus Embolic Capture balloon is also a practical option in these patients, but its single use and inability to offer protection during atherectomy limits its use. ■

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