Distal Embolization During Percutaneous Lower Limb Interventions

Identifying specific patients and lesion types that are at high risk of distal embolization could result in improved limb salvage rates and reduced morbidity and mortality.

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Although it is a relatively rare complication of endovascular therapy for patients with critical limb ischemia (CLI),[1-3] distal embolization from atherothrombotic debris still remains a concern due to the major adverse events that may follow. These complications can in turn lead to additional procedures, increased limb amputation and mortality rates, as well as extended hospital stays and escalating hospitalization costs. The amount of dislodged thromboembolic material relies on many factors, ranging from lesion characteristics to revascularization techniques and the devices used.[3,4] It has been documented that atherectomy and stent deployment induce dislodgement of more atherothrombotic material compared to percutaneous transluminal angioplasty (PTA) alone, and as expected, Transatlantic Inter-Society Consensus (TASC) C and D lesions tend to embolize more debris than lower-grade lesions.[5]

As a result of the ever-increasing demand for endovascular treatment, and therefore an increase in the complication risks (eg, distal embolization), embolic protection devices (EPDs) were developed to minimize the amount of dislodged material that reaches the distal vessels. Although the wide and indiscriminate use of these devices generates a huge increase in treatment costs without directly improving the outcomes, identifying patients who have lesions that pose a significant risk for distal embolization and might benefit from the use of the distal protection could result in improved limb salvage rates and reduced morbidity and mortality within this high-risk group.[4,6-8]

When it comes to therapy for acute limb ischemia (ALI), a handful of devices, drugs, and techniques are available. A distal embolus can be treated via thrombolytic therapy (intravenous or catheter-directed), embolectomy through aspiration, implantation of a stent graft and/or PTA, and, of course, open surgical revision.

DISTAL EMBOLIZATION

Histological examination of thromboembolic debris reveals a wide variety of materials. Amorphous materials, composed of cholesterol and macrophages, as well as fibrin, platelets, and calcium are commonly found.[9-11] Patients with ALI often present with an abrupt onset or worsening of pain and/or impairment of limb function. Paresthesia seems to occur in more than half of patients. Pulselessness and a change in skin color and/or temperature are also common findings.[12]

The incidence of distal embolization during percutaneous interventions in the lower limbs is reportedly low (occurring in approximately 1% to 5% of procedures),[1,13] and higher numbers are likely when asymptomatic cases are taken into account. Although every percutaneous procedure theoretically represents a potential risk for embolic material displacement, some interventions are at a statistically increased risk for developing ALI than others. As some studies have shown, plaque dislodgement and distal embolization are more often described after stent placement or atherectomy (laser and mechanical) than after PTA.[1,5,13,14]

Lesion characteristics should also be taken into account when analyzing a patient's risk for distal embolization. Lesions that fall under the TASC classification C or D, as well as in-stent stenosis, have markedly higher chances of producing emboli.[1,3,5]

TABLE 1. DATA FOR EPDs IN PERCUTANEOUS INTERVENTIONS IN THE LOWER LIMBS				
Author	N (Patients)	EPD Device	N (Visible Debris)	Particle Size (µm)
Shammas et al[15]	40	SpiderFX (Covidien)/ Emboshield Nav6 (Abbott Vascular)	18/45	> 2 mm
König et al[16]	11	Angioguard (Cordis Corporation)	5/9	NR
Müller-Hülsbeck et al[17]	29	FilterwireEZ (Boston Scientific Corporation)	27/30	1,200 ± 640
Karnabatidis et al[18]	48	SpiderFX	35/50	NR
Abbreviations: NR, not reported or not available.				

EMBOLIC PROTECTION DEVICES

The EPDs used in the lower limbs mainly consist of a filter in the form of a basket that is deployed distal to the target lesion after wire crossing and before any other devices are introduced (Figure 1). After the procedure, the filter is closed and removed with the emboli trapped inside. Most devices are backed by small studies with a limited number of patients. Some of those studies and devices are listed in Table 1. The use of EPDs when percutaneously treating stenotic lesions in the carotid arteries remains a topic of debate, as the results of the present studies are still somewhat discordant. Although most studies show better results in the EPD arms, a few others favor an unprotected approach.[14,19]

The deployment of EPDs also poses a risk of damaging the vessel's wall. Ex vivo studies showed some relevant damage to the tunica intima, with a controversial increase in dislodgment of debris and distal embolization.[20] In vivo, device-related adverse events have not yet been described. EPDs also do not offer protection to the side branches or for late embolism, and complete filter apposition is not always possible.

Presently, the main concern around the regular use of these devices lies more on the considerable increase in the operational costs rather than on clinical results. The relatively low incidence of distal embolization in combination with the efficacy of aspiration embolectomy or thrombolysis for bailout therapy and the risk of damaging the vessel's wall speaks against widespread adoption of the devices.

Nevertheless, EPDs remain a useful tool when treating high-risk lesions. Long chronic occlusions and extremely calcified lesions, as well as atherectomy procedures, have remarkably higher rates of debris embolization.[1,5,15] Special attention should also be given to patients with a single-vessel runoff, as the embolization and failed reperfusion could easily lead to limb loss.

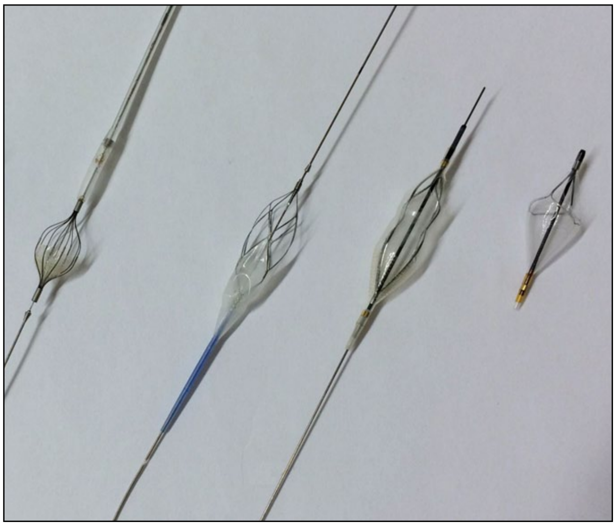


Figure 1. Some of the EPDs available. From left to right: Angioguard, RX Accunet, Emboshield, Emboshield NAV6.

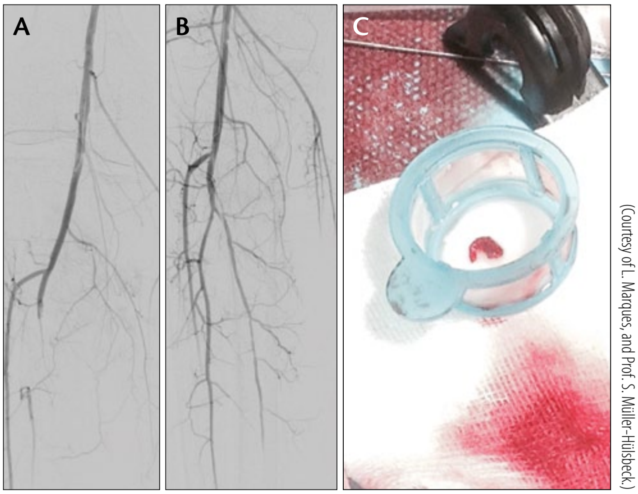


Figure 2. Angiography was performed before (A) and after (B) aspiration of embolus (C) in the tibioperoneal trunk using the Fetch2 aspiration catheter.

THERAPY

There are a few possibilities for treating acute limb ischemia caused by atherothrombotic embolization. The method of treatment should be decided after assessing the characteristics of the thrombi, such as localization, length, and time since onset.[12]

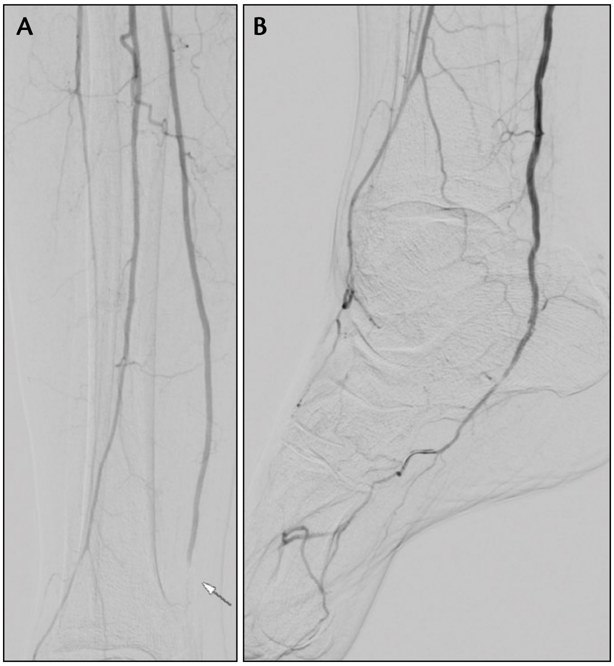
Aspiration Embolectomy

Aspiration catheters such the Fetch2 (Bayer), the Eliminate (Terumo Europe) in Europe and the PriorityOne (Terumo Interventional Systems) in the United States, as well as the Aspire (Control Medical Technology) are useful when removing soft, fresh thrombus or atheroma from distal arteries. With these catheters, a 0.014-inch guidewire is placed proximal to or passed through the affected area, and then a rapid-exchange (monorail) catheter is brought in via a ≥ 6-F sheath, according to the manufacturer's instructions for use. During aspiration, the catheter is moved back and forth, and this procedure should be repeated until the desired results are achieved (Figures 2 and 3).

There is currently very little scientific evidence on the safety, effectiveness, or complications associated with aspiration catheters when used to treat ALI in the lower limbs. There are no up-to-date larger publications or ongoing studies on the subject. Nevertheless, this method is often used in coronary interventions, in which it has shown some good results for preventing microembolization before PTA.[21-23]

Thrombolysis

The use of thrombolytic agents after a thrombogenic event in the lower extremities is well established in the literature.[15] There are different schemas for the available drugs, and Table 2 lists some of those that are most commonly used. Current clinical practice favors the use of recombinant tissue plasminogen activator and urokinase over streptokinase, although no absolute recommendation exists.[24-26] The absolute and relative contraindications for a thrombolytic therapy, according to published consensus, are synthesized in the *Contraindications to Systemic Thrombolysis* sidebar on page 74. A combination of percutaneous aspiration and local thrombolysis may help to decrease the incidence of microembolizations and therefore improve overall results (Figure 4).[27]



(Courtesy of L. Marques and Prof. S. Müller-Hülsbeck.)

Figure 3. Angiograms obtained before (A) and after (B) successful aspiration embolectomy in the distal posterior tibial artery.

Open Surgical Thrombectomy

The Fogarty catheter (Edwards Lifesciences) is the interventionist's main instrument for performing thrombectomy. Developed in the early 1960s by Dr. Thomas J. Fogarty, the catheter comprises a balloon attached to a

TABLE 2. SOME COMMONLY USED SCHEMAS IN CATHETER-DIRECTED THROMBOLYSIS

Infusion Technique	Agent	Dosage
Continuous infusion	rtPA	0.25 to 2.5 mg/h 0.05 to 0.1 mg/kg/h
	Urokinase	Low-dose technique: up to 100,000 IU/h High-dose technique: 240,000 IU/h for 4 h, then 120,000 IU/h up to 48 h
Bolus	rtPA	5-mg bolus up to 15 mg over 30 min
	Urokinase	Up to 375,000 IU over 30 min
Pulse spray	rtPA	0.1 mg every 30 s for 20 min, every 60 s afterward
	Urokinase	5,000 IU every 30 s for 20 min, every 60 s afterward

Abbreviations: IU, intravenous units; rtPA, recombinant tissue plasminogen activator.

hollow catheter, which revolutionized vascular surgery. Today, open surgical thrombectomy is becoming less and less popular with the advent of percutaneous and thrombolytic therapies, due to the longer hospital stays and costs, complications in wound management compared to the percutaneous approach, and damage to the vessel wall (especially to the intima layer).

The choice between endovascular and open surgical revascularization depends on the etiology and location of the occlusion, as well as on the contraindications to either open surgery or thrombolysis. For instance, in the treatment of suprainguinal occlusions, the surgical approach should be preferred over the endovascular, mostly due to the dimensions of the thrombi, whereas the infrainguinal arteries are best treated with endovascular therapy because the underlying causes (ie, stenosis) may be concomitantly managed.[12] When the primary treatment for ALI is not possible or fails, surgical bypass can be attempted to restore perfusion of the lower limbs.

COMPLICATIONS

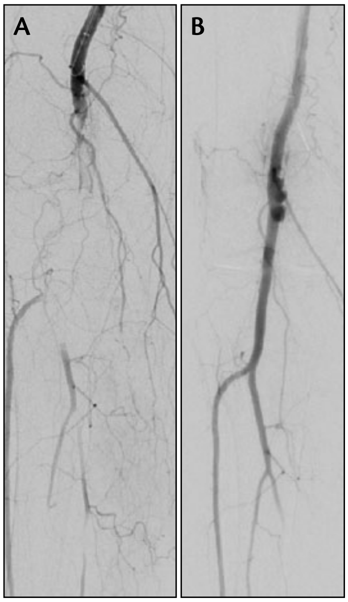
Embolization events can lead to serious complications during and/or after a percutaneous intervention. A single-center study in the UK, which included 988 patients and a total of 1,377 interventions, described a 1.5% (21/1,377) incidence of ALI after undergoing angioplasty of the lower limbs. Of those, 62% (n = 13) achieved limb salvage after embolectomy (29%, n = 6) and bypass (33%, n = 7). The remaining patients required a major amputation (38%, n = 8), and three patients (14%) died within 30 days.[3]

CONTRAINDICATIONS TO SYSTEMIC THROMBOLYSIS

Absolute Contraindications
1. Active bleeding
2. Gastrointestinal bleeding within the last 10 days
3. Intracranial trauma or neurosurgical intervention within the last 3 months
4. Established cerebrovascular event, excluding transient ischemic attack within the last 2 months

Relative and Minor Contraindications
1. Puncture of a noncompressible vessel
2. Major nonvascular surgery within the last 10 days
3. Recent eye surgery within the last 3 months
4. Major trauma within the last 10 days
5. Intracranial tumor
6. Cardiopulmonary resuscitation within the last 10 days
7. Uncontrolled hypertension (systolic > 180 mm Hg, diastolic > 110 mm Hg)
8. Hepatic failure, with coagulopathy
9. Pregnancy

Although not described in the published studies, aspiration embolectomy, like any interventional procedure, carries the risk of vessel perforation and dissection. Complications for thrombolysis are mostly related to hemorrhage. In up to 15% of interventions, minor bleeding is to be expected. Distal embolization (approximately 10%), major hemorrhage (5%), and death (1%–2%) are also reported. Most bleeding after thrombolysis is observed at the venous or arterial puncture site.[24,28]



(Courtesy of L. Marques and M. Preiss.)

Figure 4. Angiograms obtained before (A) and after (B) catheter-directed thrombolysis.

Reperfusion injuries after successful revascularization following ALI should be promptly identified and treated. It is the result of increased capillary permeability with tissue edema and may result in a compartment syndrome requiring fasciotomy. A study reported that up to 5% of patients required fasciotomy after revascularization following ALI.[12,29]

DISCUSSION

Distal embolization of dislodged debris or thrombus is a complication of percutaneous vascular interventions in the lower limbs, possibly resulting in limb amputation or death. The expected incidence of limb loss or death after distal embolization occurs in approximately 0.6% and 0.2% of the total procedures, respectively.[3,12]

Select patients with lesions that pose a higher risk of distal embolization should be evaluated, as the use of EPDs could be critical in preventing ALI during percutaneous procedures in the lower limbs. On the other hand, the widespread, uncontrolled use of such devices should be avoided because it may inflict damage to the vessel wall and increase the incidence of distal embolization in some cases. Secondarily, the economic affect should be considered, as EPDs may render the intervention too costly.[7]

CONCLUSION

We recommend the use of EPDs when performing interventions with known higher risks for distal embolization, especially atherectomy or PTA of chronic, long occlusions. We also recommend these devices when treating patients with single-vessel runoff, in whom distal embolization could lead to serious consequences.

In the event of ALI caused by distal embolization, the interventional radiologist should be prepared and able to remove the embolized material in most cases. Aspiration catheters and thrombolytic drugs should be readily available in the angiography suite. Nevertheless, it is always important to have a vascular surgeon on hand, as there are patients who may not respond well to the minimally invasive approach. Sometimes, an open surgical revision, or even bypass, could be the only way to avoid major complications like limb loss and death. ■

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