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Managing Procedural Complications During Atherectomy for Chronic Limb Threatening Ischemia: A Case Report

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ABSTRACT

Purpose: Critical Limb Threatening Ischemia (CLTI) is the most severe stage of Peripheral Artery Disease (PAD), characterized by ischemic rest pain, non-healing ulcers and gangrene. Despite advances in revascularization, CLTI remains associated with poor outcomes, including one-year mortality of 20% to 25% and major amputation rates up to 30%. Endovascular Therapy (EVT) is a less invasive treatment option, with atherectomy being particularly useful in calcified or occlusive lesions. However, Large Thrombus Burden (LTB) poses a major challenge due to increased risk of distal embolization. While Embolic Protection Devices (EPDs) aim to mitigate this, their efficacy in CLTI remains uncertain.

Methods: A 68-year-old man with PAD presented with rest pain and a non-healing ulcer on the right fifth toe. Angiography revealed subacute occlusion of the superficial femoral artery extending to the anterior tibial artery, with suspected LTB. EVT was performed using a Jetstream atherectomy device for lesion debulking and an embolic filter for distal protection. Following successful guidewire crossing and atherectomy, the procedure was complicated by acute limb ischemia due to distal embolization in the tibioperoneal trunk. Immediate thromboaspiration was performed using the Penumbra Indigo System.

Results: Thromboaspiration effectively restored distal perfusion. Post-procedural angiography confirmed full revascularization with no residual thrombus. The patient's symptoms improved and he was discharged on dual antiplatelet therapy, with follow-up planned at 1, 3 and 6 months.

Conclusion: Atherectomy in CLTI patients with LTB increases embolization risk, even with EPDs. Thromboaspiration remains a viable rescue strategy, underscoring the need for standardized protocols and further research on embolic risk mitigation.

Keywords: Critical limb ischemia, Peripheral arterial disease, Atherectomy, Endovascular procedures, Embolic protection devices, Thromboaspiration, Revascularization

1. Introduction

With an estimated prevalence of 3.1% in Europe[1] and more than 236 million worldwide[2] PAD still represent a significant growing public health concern worldwide[2-3]. CLTI represents the most advanced stage of PAD and is associated with a substantial risk of limb loss and overall cardiovascular mortality. Defined by the presence of ischemic rest pain, non-healing ulcers or gangrene, CLTI occurs as a consequence of severely compromised perfusion to the lower extremities due to multilevel arterial obstruction[4]. The burden of CLTI is growing in parallel with the global rise in diabetes, hypertension and chronic kidney disease-key risk factors that not only predispose to PAD but also accelerate its progression[5]. Despite advancements in limb salvage techniques, the five-year mortality for CLTI approaches 60% and amputation-free survival remains suboptimal[6]. Revascularization, either via surgical bypass or EVT, is the cornerstone of treatment, aiming to restore adequate perfusion, alleviate ischemic symptoms and promote wound healing.

Endovascular-first strategies have become increasingly common in contemporary practice, particularly among high-risk surgical candidates[7]. Specifically, atherectomy has emerged as a valuable adjunctive technique for lesion preparation in infrainguinal disease, particularly in cases with severe calcification or long-segment occlusions[8]. By debulking atherosclerotic and thrombotic material, atherectomy enhances luminal gain and improves the efficacy of adjunctive therapies such as balloon angioplasty or drug-eluting devices.

One of the most significant procedural challenges during atherectomy is distal embolization, especially in the presence of a LTB[9]. EPDs may be used in those cases to mitigate this complication, but their performance in peripheral interventions remains variable and heavily dependent on anatomical factors, operator technique and the nature of the lesion itself[10].

We report the case of an acute limb ischemia due to thrombus migration in a patient with CLTI undergoing superficial femoral artery recanalization with Jetstream atherectomy system successfully treated with Emergent thromboaspiration using the Penumbra Indigo System.

2. Case Report

A 72-year-old man presented to the emergency department in July 2023 due to an 8-hour history of left lower extremity increasing pain without sensory loss. Body temperature and vital signs were normal despite on clinical examination the presence of infected trophic ulcers on the first and fourth toes were noticed. The patient's past medical history was significant for poorly controlled type II diabetes mellitus, hypertension, dyslipidemia, a prior clavicular fracture, surgical repair of an umbilical hernia and hemorrhoidectomy. At the time of presentation, he was on a domiciliary pharmacological regimen consisting of subcutaneous human insulin (8 IU before meals), ramipril (5 mg, twice daily) and atorvastatin (40 mg, once daily).

Specifically, regarding patient vascular medical history, he had two prior Percutaneous Transluminal Angioplasties (PTA) of the right Superficial Femoral Artery (SFA) for Leriche-Fontaine stage IIb PAD, performed in June 2019 and July 2020, respectively. Despite no clinical documentation of the previous angioplasty was available at the moment of admission. On clinical examination, the absence of peripheral pulses of the left lower limb was noticed. On duplex ultrasound bilateral monophasic post-stenotic Doppler waveforms in the tibioperoneal district was noticed, with no arterial flow below at the SFA and an ankle brachial index of 0.7.

A contrast enhanced computed tomography was requested, demonstrating the complete chronic occlusion of the SFA, with partial recanalization at hunter's canal level.

Based on clinical findings, patient's comorbidity and extension of disease, a total endovascular approach was considered appropriate. After obtaining ultrasound guided access of the right Common Femoral Artery (CFA) a 7F reinforced introducer sheath was advanced into the left External Iliac Artery (EIA). Diagnostic angiography demonstrated patency of the left Profunda Femoris Artery (PFA) and confirmed the complete occlusion of the left SFA (Figure 1) and patency of the popliteal artery, peroneal artery, Posterior Tibial Artery (PTA) and plantar arch. A focal subocclusive stenosis at the origin of the Anterior Tibial Artery (ATA) was also noted.

Figure 1: Fist diagnostic intraoperative angiography showing the patency of the left PFA and the complete occlusion of the left SFA.

Despite the sub-acute occlusion of the SFA, the distal run-off was deemed favorable. Recanalization of the SFA was attempted with Jetstream Atherectomy System (Boston Scientific, Marlborough, MA) so, after crossing the SFA occlusion with 0.018" guidewire an Emboshield NAV6 Embolic Protection System was deployed at P1 level of the popliteal artery for further protection for distal embolization (Figure 2).

Recanalization was then completed with sequential balloon angioplasty with 5 x 120 mm and 5 x 200 mm drug-eluting balloons. Post-procedural angiography showed successful SFA recanalization, with segmental dissections and focal residual stenosis distal to the SFA origin. The embolic filter was subsequently retrieved but the completion angiography revealed the presence of embolic debris at the tibioperoneal trunk level consistent with a clinical presentation of acute limb ischemia (Figure 3).

Figure 2: Positioning of the Emboshield NAV6 at the P1 segment of the popliteal artery.

Figure 3: Completion angiography showing the presence of embolic debris at tibioperoneal trunk level.

Consequently, thromboaspiration with Penumbra System was attempted (Penumbra Inc., Alameda, CA, USA), with satisfactory reperfusion of the tibioperoneal trunk and plantar arch (Figure 4).

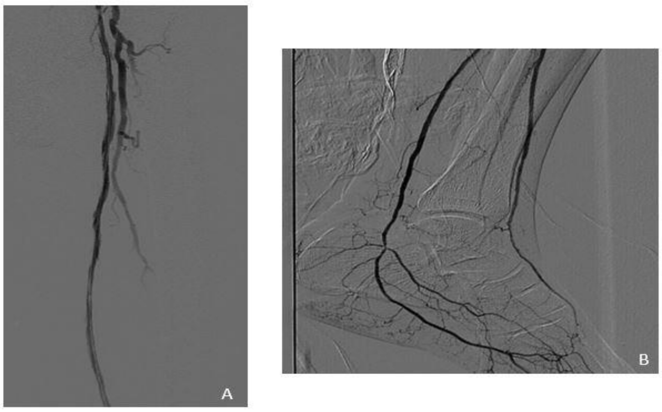

Figure 4: (A) Patency of the superficial femoral artery with distal peroneal artery wall irregularities and improved anterior tibial artery perfusion. (B) Complete revascularization of the plantar arch.

Three days post-procedure, the patient showed elevated inflammatory markers, (Table 1) with swelling and pain of the left foot consistent with an ongoing infection. A microbiological swab of the trophic ulcer located on the third toe of the right foot was performed and the result was positive for Streptococcus agalactiae (Group B Streptococcus).

Table 1: Postoperative day 3 patient's laboratory findings.

Test	Results	Reference Range
White Blood Cell Count (WBC)	11.5	4.0 - 10.0 x 10^9/L
C-Reactive Protein (CRP)	12.3	<5 mg/L
Procalcitonin (PCT)	0.4	<0.5 ng/mL
Platelet Count (PLT)	230	150 - 450 x 10^9/L
Hemoglobin (Hb)	13.2	13 - 17 g/dL
Hematocrit (Hct)	40.50%	40% - 50%
Blood Glucose (BG)	160	70 - 100 mg/dL
Creatinine (Cr)	0.9	0.7 - 1.2 mg/dL
Blood Urea Nitrogen (BUN)	16	7 - 20 mg/dL
Aspartate Aminotransferase (AST)	22	0 - 35 U/L
Alanine Aminotransferase (ALT)	18	0 - 40 U/L
Alkaline Phosphatase (ALP)	65	40 - 150 U/L
Total Bilirubin (T Bil)	0.6	0.1 - 1.2 mg/dL
Albumin (Alb)	3.8	3.5 - 5.0 g/dL
Sodium (Na)	141	135 - 145 mmol/L
Potassium (K)	4.2	3.5 - 5.0 mmol/L
Chloride (Cl)	101	98 - 107 mmol/L

Empiric antibiotic therapy was initiated with clindamycin 600 mg every 8 hours and ampicillin/sulbactam 3 g every 6 hours that was continued, in light of confirmatory results from the microbiological culture, for a total duration of 22 days (Table 2).

Table 2: Antibiotic susceptibility profile (antibiogram) for *Streptococcus agalactiae* isolated from trophic ulcer swab.

Antibiotic	Susceptibility Result	Interpretation
Penicillin	0.03 μg/mL	Susceptible
Ampicillin	0.06 μg/mL	Susceptible
Cefotaxime	0.25 μg/mL	Susceptible
Erythromycin	>8 μg/mL	Resistant
Clindamycin	0.12 μg/mL	Susceptible
Vancomycin	0.5 μg/mL	Susceptible
Linezolid	1 μg/mL	Susceptible
Tetracycline	>16 μg/mL	Resistant
Levofloxacin	1 μg/mL	Susceptible
Trimethoprim/ Sulfamethoxazole	>4/76 μg/mL	Resistant (intrinsic)
Daptomycin	0.25 μg/mL	Susceptible

Despite the initiation of appropriate antibiotics, clinical examination revealed persistent infection and deterioration of the fourth left toe so after careful consideration and informed consent of the patient a selective amputation of the left fourth toe at the metatarsophalangeal joint was performed, the procedure led to the complete resolution of the infection and the patient was discharged at the postoperative day 30. showed significant clinical improvement.

At the 6-month follow-up visit, a Doppler ultrasound was performed, confirming that the previously treated arterial segments remained patent. Both the tibioperoneal trunk and plantar arch showed excellent perfusion, with no signs of restenosis.

3. Discussion

CLTI represents the most advanced and severe clinical stage of PAD, affecting approximately 1.8% of individuals over the age of 50 and up to 10% of patients with diabetes or end-stage renal disease[11]. CLTI is characterized by ischemic rest pain, non-healing ulcers and gangrene and it carries a dismal prognosis if left untreated[12]. The one-year mortality rate for patients with CLTI ranges from 20% to 25% and the five-year mortality approaches 60%[13]-figures that rival or exceed many common malignancies. Additionally, major amputation occurs in up to 30% of patients within one year of diagnosis, particularly in those who do not undergo timely revascularization[14]. Therefore, prompt and effective revascularization-either through endovascular or surgical means-is essential not only for limb salvage, but also for improving functional outcomes and reducing all-cause mortality. Successful revascularization can reduce the risk of major amputation up to 50% and improve one-year limb salvage rates to over 80%, underscoring its central role in CLTI management[15-16]. In recent years, endovascular therapy has increasingly supplanted open surgical bypass as the first-line treatment modality for CLTI, especially in patients with advanced age or multiple comorbidities such as diabetes, renal insufficiency or coronary artery disease. This paradigm shift is supported by a growing body of evidence, beginning with the pivotal BASIL trial that showed no significant difference in amputation-free survival at 1 year (approximately 68% in both groups), despite suggesting a late survival advantage for surgery in patients who survived more than two years, particularly when a good-quality vein conduit was available[17].

However, these findings were nuanced by subsequent observational studies and registries, such as those derived from the Vascular Quality Initiative (VQI), which reported that endovascular-first strategies were associated with lower 30-day morbidity, shorter hospital stays (median 3 *vs.* 7 days) and reduced perioperative mortality (1.2% vs. 3.0%) compared to open bypass in high-risk patients[18].

More recently, the BEST-CLI trial[19] provided high-level evidence with over 1,800 patients enrolled across two parallel cohorts. In patients with a suitable single-segment great saphenous vein (cohort 1), surgical bypass demonstrated superior outcomes, with a 32% relative risk reduction in major adverse limb events or death at median follow-up of 2.7 years compared to endovascular treatment. However, in cohort 2, which included patients without suitable vein conduits, no significant difference in primary outcomes was observed, reaffirming the role of endovascular therapy in patients with limited surgical options.

Furthermore, the ongoing BASIL-2[20] and BASIL-3[21] trials are expected to provide more granular insights into outcomes of vein bypass *vs.* endovascular interventions in below-the-knee and multi-level disease, but interim results already suggest that patient selection, conduit availability and anatomical complexity are critical factors in determining the optimal revascularization strategy.

Despite the potential advantage of longer-term patency with open bypass in carefully selected patients, the less invasive nature of endovascular intervention, combined with lower immediate complication rates and faster recovery, makes it the preferred initial strategy in many contemporary vascular centers[22].

In the case presented, the total endovascular approach was favored due to the patient's comorbid conditions, including poorly controlled diabetes, hypertension and prior cardiovascular events. Moreover, the anatomy demonstrated on imaging, including a chronic occlusion of the Superficial Femoral Artery (SFA) with favorable distal runoff, was amenable to percutaneous intervention. Endovascular-first strategies are especially beneficial in such scenarios, avoiding the morbidity associated with open bypass, including wound infection, longer hospital stay and anesthesia-related complications.

The use of atherectomy, specifically with the Jetstream system, was chosen to debulk the lesion and modify the underlying plaque, given the high likelihood of a thrombotic component overlying an atherosclerotic plaque. Atherectomy can be particularly advantageous in lesions with heavy calcification or long chronic total occlusions, as it improves vessel compliance and luminal gain, facilitating the efficacy of adjunctive therapies such as drug-coated balloon angioplasty. However, a significant risk associated with atherectomy is distal embolization, particularly in the context of thrombotic lesions[23].

In this case, an EPD was used prophylactically during the procedure, despite not being mandatory in the Jetstream system's official indications[23]. This decision was based on a preoperative assessment that suggested a high embolic risk. The pathophysiology of the occlusion-thrombosis superimposed on an atherosclerotic plaque-combined with the clinical presentation of chronic ischemia and claudication, heightened concern for embolic complications. The literature supports such individualized decisions, considering that up to 25% of patients undergoing atherectomy for lower extremity disease experience some degree of distal embolization, which can lead to acute limb ischemia or subclinical perfusion deficits[24].

Despite the use of an EPD and meticulous procedural planning, the patient developed acute limb ischemia due to distal thrombus embolization into the Tibi peroneal trunk following filter retrieval. All vessel measurements, including luminal diameters, landing zones and segmental anatomy, were accurately obtained prior to device deployment using high-resolution angiography and intravascular imaging to ensure appropriate filter sizing and positioning. However, embolization still occurred, likely due to a combination of anatomical and procedural factors that overwhelmed the protective capacity of the EPD.

Several mechanisms may explain this adverse event. First, suboptimal filter positioning, even by a few millimeters, can result in incomplete protection of the at-risk segment. If the filter is deployed too proximally or distally relative to the primary embolic source-such as a heavily diseased segment or a thrombosed lesion-debris dislodged during angioplasty or atherectomy may bypass the filter altogether. Even under fluoroscopic guidance, exact positioning can be challenging, especially in tortuous or calcified vessels.

Second, filter under sizing relative to vessel diameter may have resulted in incomplete wall apposition. Although all measurements were performed, vessel compliance, eccentric plaque or dynamic changes in diameter during the cardiac cycle can lead to subtle mismatches between the filter's radial force and the arterial wall. These gaps create potential channels for embolic material to escape around the filter, a recognized limitation particularly in vessels with diffuse disease or luminal tapering[25].

Third, the "toothpaste effect" during device retrieval likely contributed to the embolic event. This phenomenon, well-documented in the literature, refers to the extrusion of soft, friable thrombotic material through the filter mesh when the retrieval sheath is advanced over the device[26,27]. If the thrombus is not firmly ensnared or if the retrieval is performed too rapidly, the compressive force of the sheath can displace material distally, even in the absence of overt technical error.

Fourth, the presence of a LTB. LTB refers to the accumulation of a substantial volume of thrombus within an artery, often superimposed on a background of severe atherosclerotic plaque. Despite LTB not being well-documented in patients with CLTI, but mainly for the coronary district[28], similar challenges may occur in peripheral interventions. This is particularly common in patients with CLTI who experience subacute ischemic events. In such cases, a previously narrowed artery-already compromised by chronic plaque buildup-becomes acutely or sub acutely occluded by fresh thrombus. These fresh thrombi are typically soft, friable and poorly organized, making them highly prone to fragmentation and embolization when disturbed, such as during endovascular interventions like atherectomy. This vulnerability significantly raises the risk of distal embolization, which can worsen limb perfusion, complicate the procedure and potentially lead to poorer outcomes[29].

The likely underlying motivation for this embolization event is multifactorial: the presence of a large thrombus burden, combined with fragile, non-calcified material that was prone to fragmentation, may have exceeded the capture capacity of the EPD. In such cases, filter-based devices may provide only partial protection. Additionally, procedural manipulation and mechanical stress during retrieval likely exacerbated the risk, particularly if there was any delay between embolic capture and device removal, allowing thrombus softening or displacement.

To mitigate these complications, a few strategies can be considered. A careful preoperative planning with intravascular imaging or high-resolution CTA can help assess plaque morphology, thrombus burden and vessel dimensions[30]. Then a proper sizing and deployment of the embolic filter is essential to ensure full apposition to the vessel wall. Moreover, to consider an alternative embolic protection strategy-such as aspiration catheters or proximal occlusion balloons-may be considered in selected high-risk lesions, although these approaches are technically more demanding[31].

In this case, the complication was successfully managed with immediate thromboaspiration using the Penumbra Indigo System, an aspiration-based mechanical thrombectomy device that has demonstrated high efficacy in the treatment of acute peripheral thrombotic events. The INDIAN trial[32], have reported technical success rates exceeding 90% in patients with acute limb ischemia, with significant restoration of perfusion and low periprocedural complication rates. The decision to employ the Penumbra system was further supported by the logistical and technical convenience of its use within the existing endovascular setup-catheter-based access was already established and the procedural team was well-equipped and trained in aspiration techniques. This facilitated a seamless transition from revascularization to thrombus management, without the need to escalate to an open surgical conversion. The availability of effective bailout tools within the endovascular arsenal, combined with real-time clinical judgment, underscores the critical role of operator experience, procedural planning and the adaptability of endovascular therapy in managing intraprocedural complications.

It is worth emphasizing that the success of endovascular therapy in CLTI relies heavily on operator expertise, comprehensive preprocedural planning and awareness of potential complications. Advanced endovascular skills are necessary not only for crossing complex lesions but also for managing complications such as embolization, dissection or vessel perforation. The endovascular approach, while less invasive, does not eliminate procedural risks and requires a thorough understanding of device mechanics and lesion pathology.

Moreover, the presence of an underlying infection, as seen in this patient, further complicates the clinical picture. Infected wounds increase the risk of systemic complications and may compromise procedural outcomes. Despite adequate revascularization and initiation of targeted antibiotic therapy, progression of soft tissue infection in the fourth toe necessitated surgical amputation. This underscores the importance of a multidisciplinary approach in the management of CLTI, integrating vascular surgery, infectious disease, diabetology and wound care expertise to optimize limb salvage outcomes.

Follow-up imaging at six months confirmed sustained vessel patency, with clinical improvement and resolution of ischemic symptoms. This outcome reinforces the potential of endovascular-first strategies in achieving favorable medium-term results in appropriately selected patients. However, long-term surveillance remains essential, as restenosis rates following atherectomy and angioplasty can be significant, particularly in diabetics and those with diffuse distal disease.

4. Conclusion

This case highlights both the therapeutic potential and the procedural challenges of endovascular-first strategies in managing chronic limb-threatening ischemia. Atherectomy remains a valuable option for complex femoropopliteal occlusions, particularly in patients with significant comorbidities and favorable distal runoff. However, the risk of distal embolization-especially in the presence of large thrombus burden-persists despite the use of embolic protection devices. Prompt recognition and effective management of such complications exemplifies that procedural success in CLTI extends beyond recanalization, it demands a multidisciplinary, complication-aware strategy tailored to lesion morphology and patient-specific risk. Future improvements in embolic protection and real-time thrombus characterization may further refine safety and outcomes in complex infrainguinal interventions.

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