

# Intraprocedural Distal Embolization After Femoropopliteal Angioplasty: Is There a Role for Below-the-Knee Stents?

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## Abstract

**Purpose** Intraprocedural distal embolization is an accepted complication of femoropopliteal angioplasty. The purpose of this study is to assess the use of below-the-knee stents in the “bail-out” of conventional methods.

**Materials and Methods** We retrospectively reviewed 1485 of femoropopliteal angioplasties that were performed in our centre in a 4-year period and analysed 12 cases (<1%) where distal embolization that required further intervention occurred. In all cases lesions were chronic and 75% suffered from critical limb ischaemia. The target vessel was the SFA in all of the cases with a long (>10 cm) occlusion in 50%. A three-vessel run-off was present in only 25%. Patients that received a stent as a limb salvage attempt were analysed. Outcome measures were technical success, clinical success and procedure-related complications. Multivariate regression analysis of the factors related to stenting was also performed.

**Results** In 41% of the cases with distal embolization, recanalization with aspiration, thrombolysis or angioplasty offered a satisfactory result. In 59%, conventional methods were ineffective; a stent was deployed in 85%, whereas in 15% surgical embolectomy was required. Technical and clinical success of the stent cases was 100% without any procedure-related complications. There was significance ( $p < 0.05$ ) between critical limb ischaemia and stenting; single-vessel run-off has also shown a positive trend ( $p = 0.88$ ).

**Conclusion** Stents appear as a valid salvage option for infragenicular distal embolization when conventional methods fail; the likelihood of having to use a stent is higher for patients with critical limb ischaemia and a single-vessel run-off.

**Keywords** Peripheral vascular interventions · Distal embolization · Below-the-knee stents · Complications

## Introduction

Angioplasty and stenting of the femoropopliteal arteries is the standard of care for the majority of patients with intermittent claudication or critical limb ischaemia [1]. Intraprocedural distal embolization after femoropopliteal angioplasty is an accepted phenomenon; studies with the use of distal protective filters have shown that elements of thrombus and atheromatous plaque are migrating distally in more than 50% of angioplasty cases [2]. However, clinically significant events that lead to main vessel occlusion and would require intervention occur in approximately 1–1.5% of cases [3].

Endovascular treatment strategy in such occasions consists in aspirating, displacing or lysing the thrombus, and a variety of endovascular tools can be used on this purpose (aspiration devices and catheters, balloons, rheolytic and mechanical thrombectomy catheters, pharmacological thrombolysis, etc.) [4–10]. However, there are cases where thrombus cannot be completely aspirated or where thrombolysis cannot be applied or even where recanalization manoeuvres damage to the underlying vessel and the final result is suboptimal.

The use of stents is established for the “bail-out” of angioplasty in the infrainguinal territory, offering excellent long-term results for atherosclerotic lesions [11, 12]. Their

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effect for the “bail-out” of ineffective thrombolysis, balloon angioplasty or thrombus aspiration in the event of intraoperative distal embolization of femoropopliteal lesions has not been evaluated until today.

The purpose of this study is to assess the role of infragenicular stents as a “bail-out” of conventional methods in patients with intraoperative distal embolization after femoropopliteal angioplasty performed for the treatment of intermittent claudication or critical limb ischaemia.

## Materials and Methods

This is a single-centre retrospective analysis. Patients that underwent femoropopliteal angioplasty for intermittent claudication or critical limb ischaemia for a 4-year period (January 2012 to February 2016) were evaluated. The patients from this cohort that underwent any type of intervention (endovascular or surgical) due to intraoperative distal embolization were then included in the study. Patient data were extracted from the hospital electronic records and the records of the local morbidity and mortality meeting. A medical student and an interventional radiology (IR) fellow, under the supervision of an IR consultant, gathered the data. All data were collected as a part of routine clinical care, and patient treatment was not influenced by the study. No patient contact was required. An institutional audit review board approved the study, and informed consent was waived.

Patients were referred for endovascular treatment to alleviate signs and symptoms of peripheral vascular disease ranging from claudication to critical limb ischaemia (rest pain, foot ulceration/gangrene). All patients were reviewed by a vascular surgeon and underwent duplex ultrasound and/or computed tomography angiogram (CTA) of the peripheral vessels of the lower limbs prior to intervention.

In total, 1485 patients were initially assessed. Distal embolization that required further intervention occurred in twelve patients (0.8%); 6 were males and 6 females, and mean age was 75 years (range 49–90 years). In 9/12 cases patients suffered from critical limb ischaemia and in 3/12 from disabling claudication. In all cases lesions were chronic. The target vessel was the right superficial femoral artery (SFA) in 9/12 cases and the left SFA in 3/12. In 6/12 cases the target lesion was a tight stenosis, in 5/12 a long (>10 cm) occlusion and in 1/12 cases in-stent restenosis. A three-vessel run-off was present in 3/12 cases, a two vessel in 5/12 and a single vessel in 4/12. Patient and lesion characteristics are shown in Table 1.

## Procedure

In 11/12 cases an antegrade approach was used. The lesions were crossed using suitable wires and catheters and

angioplastied with balloons of appropriate size. As per our standards of practice, all patients received between 3000 and 5000 international units (IU) of heparin intra-arterially prior to negotiation with the lesion, to mitigate the risk of distal embolization. Post-angioplasty angiogram followed to assess distal vessels. If distal embolization occurred, catheterization of the occluded vessel and an angioplasty or clot aspiration attempt was initially performed. The balloons used were either 2–3.5 mm in diameter (Sterling, Boston Scientific Inc), and the aspiration was performed either via an end-hole angiographic catheter and a 50-ml syringe with manual aspiration or with the use of a dedicated aspiration device (Indigo, Penumbra Inc). Thrombolysis was administered either as a bolus of 5 mg of rTPA or via an overnight infusion pump at a rate of 10 mg/h. If a decision for a stent was made, a balloon-expandable drug-eluting device (Promus, Boston Scientific) was used. If a stent were to be used, a loading dose of 300 mg of clopidogrel followed by a dual antiplatelet therapy of aspirin and clopidogrel for 6 months was administered.

## Outcome Measures and Statistical Analysis

The indication for stenting in the vessels below the knee was an angiographically proven intraoperative thromboembolic event compromising blood flow that did not respond to clot aspiration, thrombolysis or angioplasty. The outcome measures were technical success, clinical success and procedure-related complications of the cases that received a stent. Technical success was defined as the angiographically proven revascularization of the occluded segment with the outcome of at least one run-off vessel; clinical success was defined as the non-deterioration of symptoms related to peripheral vascular disease after the embolic event; procedure-related complications were classified as early if occurred in the first 30 days after stent placement, otherwise they were classified as late according to the North American Society of Interventional Radiology (SIR) criteria [13, 14]. Multivariate regression analysis of the factors related to stenting was also performed. Statistical analysis was performed with IBM® SPSS® version 24 program.

## Results

In 5/12 cases (41%) recanalization with aspiration, thrombolysis or angioplasty offered a satisfactory result. In 7/12 cases (59%) conventional methods were ineffective; a stent was deployed in 6/7 (85%), whereas in 1/7 (15%) surgical embolectomy was required. The age range of the patients that received a stent was 77.1 years (range 49–90 years), and there were 3 males and 3 females. In 3/6

**Table 1** Patient and lesion characteristics

Age	Procedure indication	Target vessel	Target lesion	Below-the-knee vessels
81	Critical limb ischaemia	Right SFA	Tight stenosis	Single peroneal
76	Critical limb ischaemia	Right SFA	Stenosis	Single peroneal
50	Disabling claudication	Right SFA	Stenosis	Three vessel
88	Critical limb ischaemia	Right SFA	Long occlusion	ATA and peroneal
90	Critical limb ischaemia	Left SFA	Long occlusion	ATA and peroneal
81	Critical limb ischaemia	Left SFA	Stenosis	PTA and peroneal
87	Critical limb ischaemia	Right SFA	Long occlusion	ATA and peroneal
84	Disabling claudication	Right SFA	Tight stenosis	Single peroneal
49	Critical limb ischaemia	Right SFA	Stenosis	ATA (proximal) and peroneal
80	Critical limb ischaemia	Right SFA	Long occlusion	Single peroneal
64	Disabling claudication	Right SFA	In-stent restenosis	Three vessel
70	Critical limb ischaemia	Left SFA	Long occlusion	Three vessel

SFA superficial femoral artery, ATA anterior tibial artery, PTA posterior tibial artery

case the underlying lesion was an SFA occlusion and in 3/6 an SFA stenosis. The mean length of the occlusion was 11.8 cm. In 3/6 cases a single-vessel run-off was present, and in 3/6 two vessels were patent. All cases were affected by critical limb ischaemia, and 2/6 patients were diabetic. In 4/6 cases embolization occurred after balloon deployment post-intraluminal recanalization, in 1/6 after angioplasty of a subintimal tract and in 1/6 post-SFA stent deployment. In 6/6 cases aspiration and angioplasty were performed as an initial salvage method. Aspiration was performed via an end-hole 5-Fr catheter and a 50-ml syringe with manual aspiration in 6 cases, and in one case the Indigo© (Penumbra Inc) aspiration system was also used. In none of the cases thrombolysis was attempted.

In total, 7 stents were deployed; two 4 × 38 mm stents in the tibioperoneal trunk, 3.5 × 28 mm and 3.5 × 38 mm stents in the peroneal and 3 × 28 mm, 3.5 × 28 mm and 3.5 × 38 mm stents in the AT (Figs. 1, 2).

Technical success as defined previously was 100% with establishment of flow to at least one of the run-off vessels on angiography. However, in 2/6 cases flow was limited to one of the previously patent vessels. In both those cases the ATA and the peroneal were the two run-off vessels and a decision was made to salvage the ATA because it appeared as predominant vessel in the baseline scan. In one case attempt to salvage the peroneal with angioplasty was performed but without success (Fig. 2).

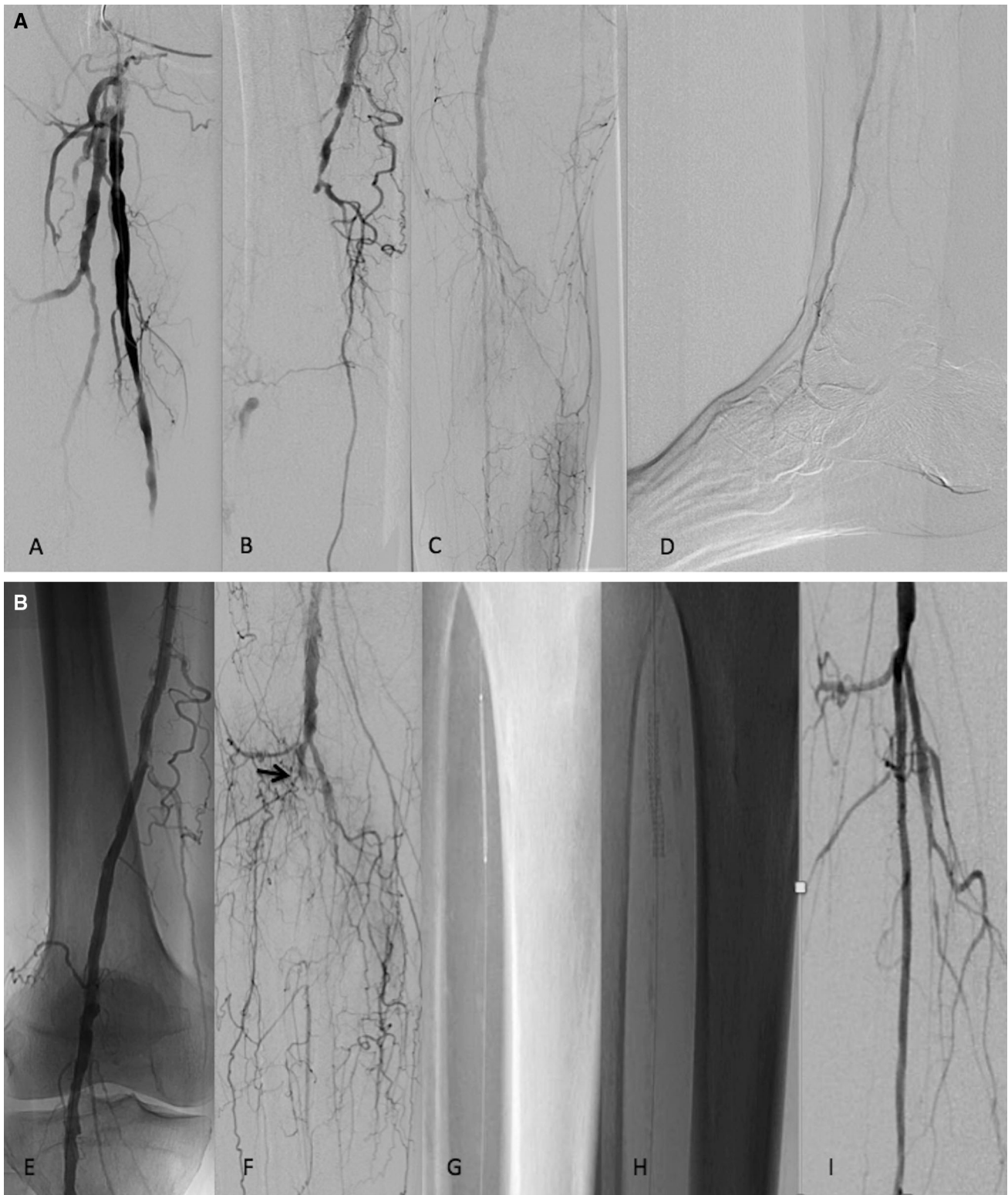
Clinical success information was obtained in 4/6 cases. A 90-year-old patient died 9 days post-procedure due to other causes, and a 49-year-old diabetic patient with advanced osteomyelitis that pre-existed the angioplasty underwent a below-the-knee amputation 1 month post-procedure. The amputation was scheduled prior to the angioplasty, and the reason for the angioplasty was to improve stump healing so the embolic event did not

influence the course of disease. In the 4/6 cases where follow-up is available, ulcer healing was achieved in all cases with 100% clinical success. Stent patency at 1 year was 100%. One patient died at 1 year and 8 months post-stenting with the stents patent, and three patients are still alive. One patient underwent new angioplasty at 1 year and 1 month due to in-stent stenosis, and two of the patients have documented patency on duplex of 1 year and 4 months and 2 years and 9 months. The results of the patients that received a stent are shown in Table 2.

Multivariate logistic regression analysis of factors related to the stent deployment was performed including three different factors: critical limb ischaemia, occlusion of the target vessel (SFA) and the presence of a single run-off vessel. The likelihood ratio test has shown that critical limb ischaemia was significantly correlated with the use of stents ( $p < 0.05$ ) and there was trend of significance for the presence of a single run-off vessel ( $p = 0.088$ ) towards stenting, whereas the occlusion of the target vessel showed no correlation at all ( $p = 0.997$ ). The results of the regression analysis are shown in Table 3.

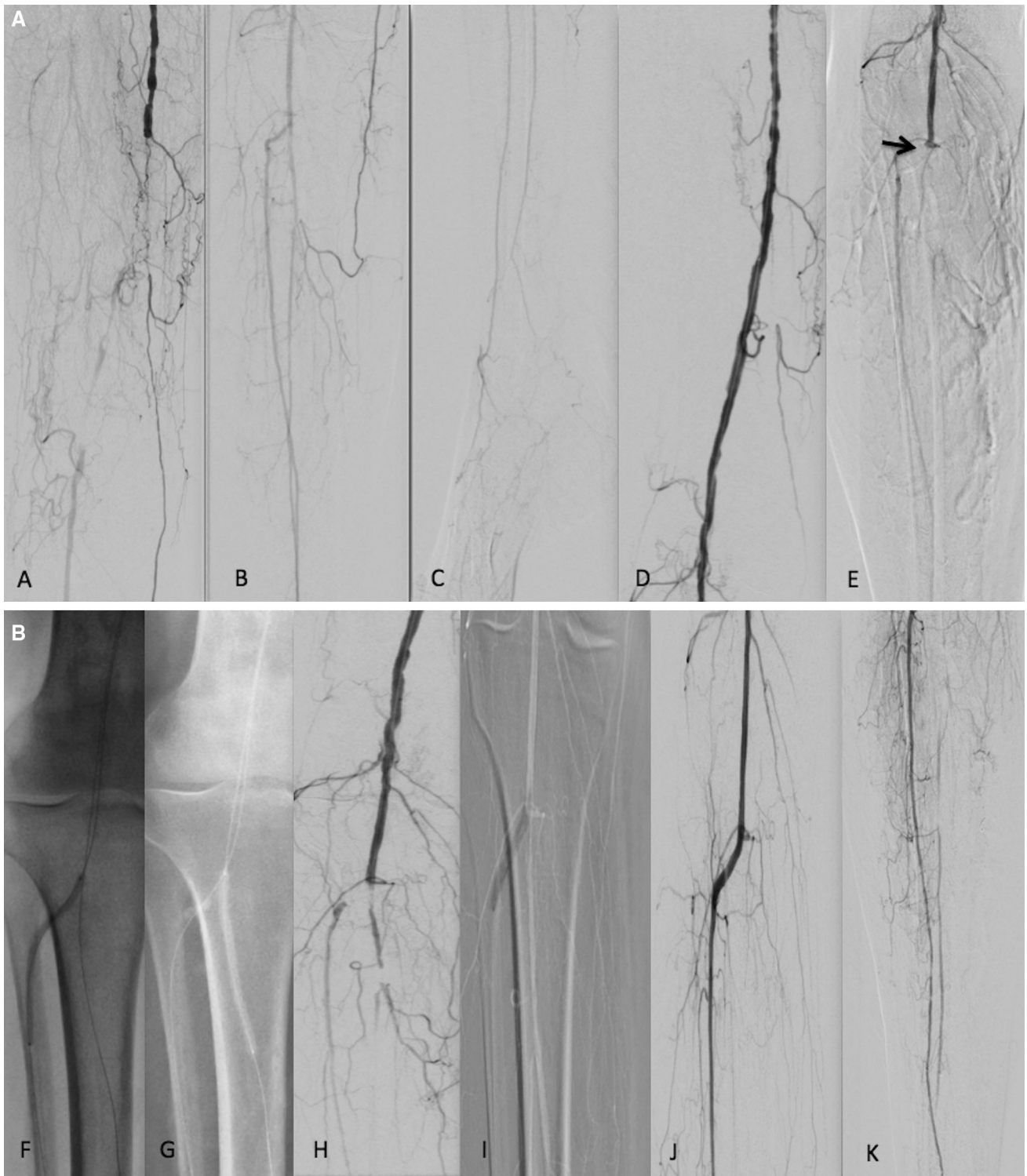
## Discussion

Distal embolization following lower limb intervention remains a rare but serious complication with an incidence of limb loss or even death at 0.6 and 0.2%, respectively [15, 16]. The probability of distal embolization depends not only on the lesion characteristics, but also on the length of the procedure and the type of devices used [15, 17, 18]. It has been reported that distal embolization complicates stent placement or atherectomy more than plain balloon angioplasty [19–21]. Worse outcomes following distal embolization are seen in diabetic patients and those with



**Fig. 1** **A** 81-year-old male with rest pain in the right foot and a history of previous popliteal and tibial angioplasty 2 years ago. DSA demonstrates **A** severe distal SFA disease with occlusion of the popliteal at the level of P1 and **B** reconstitution at the level of P2. **C**, **D** Occluded peroneal and PT with a patent TP trunk and single-vessel

run-off via the AT. **B E** Popliteal occlusion crossed and angioplastied. **F** Distal embolization with occlusion of the AT (*arrow*) which is the main run-off into the foot. **G**, **H** Occlusion crossed with a wire and deployment of a 3 × 28 mm everolimus-eluting stent. **I** Run-off re-established in the AT with good flow distally



**Fig. 2** A 87-year-old female with short distance claudication in the right leg. **A** Distal SFA and proximal popliteal occlusion at the level of P1 with reconstitution at the level of P2 via collaterals. **B** Patent TP trunk, AT and peroneal with an occluded PT. **C** Distal run-off into the foot via the AT. **D** The femoropopliteal occlusion was crossed and angioplastied. **B E** Complicated by distal embolization to the AT and

peroneal (*arrow*), compromising run-off. **F** An 0.018 wire was successfully used to cross the occlusions in the peroneal and AT which were angioplastied (**G**) with a suboptimal result (**H**). A 4 mm × 28 mm everolimus-eluting stent was deployed in the AT (**I**), main run-off vessel, with a resultant re-establishment of flow (**J**) and good flow into the foot (**K**)

**Table 2** Results of patients that received a stent

Age	81	76	90	87	49	80
Diabetic	No	Yes	No	No	Yes	
Embolization	Right peroneal (proximal)	Right TP trunk	Distal popliteal	Distal popliteal	Proximal peroneal	Distal popliteal
Cause of embolization	Angioplasty	Angioplasty	Angioplasty	Stent deployment	Angioplasty	Stent deployment (re-entry device)
Aspiration	5-Fr end-hole catheter	5-Fr catheter and Indigo system	5-Fr end-hole catheter	5-Fr end-hole catheter	5-Fr end-hole catheter	5-Fr end-hole catheter
Balloon (mm)	2.5 and 3	3	3	3	3	3.5
Lysis	No	No	No	No	No	No
Stent (mm)	3 × 28	4 × 38	3.5 × 28	4 × 28	3.5 × 38 and 3.5 × 28	4 × 38
Technical outcome	Good	Good	Peroneal blocked	Peroneal blocked	Good	Good
Follow-up	Duplex	Clinic	None	Duplex	None	Duplex
Patency	2 years and 9 months	1 year and 8 months	Unknown—died 9 days later from other causes	1 year and 4 months	Below-knee amputation due to advanced osteomyelitis 1 month later	Stenosis at 1 year and 1 month—plasty with a 4-mm balloon
Patient status	Alive	Dead	Dead	Alive	Alive	Alive
Clinical outcome	Ulcer healed	Ulcer healed	Unknown	Ulcer healed	Unknown	Ulcers healed

**Table 3** Multivariate logistic regression analysis of factors related to the stent deployment

Effect	Model fitting criteria −2 log likelihood of reduced model	Likelihood ratio tests		
		Chi square	df	Sig.
<i>Likelihood ratio tests</i>				
Intercept	3.348 <sup>a</sup>	.000	0	
Critical limb ischaemia	9.146	5.798	1	.016
Target vessel occlusion	3.348	.000	1	.997
Single-vessel run-off	6.259	2.911	1	.088

The last column indicates the correlation of each parameter with the likelihood of stenting with significant values <0.05. Critical limb ischaemia appears to be the only significantly correlated factor with the likelihood of stent deployment

chronic kidney disease [22, 23]. Nevertheless, it is difficult to predict when distal embolization will occur. Among 1485 cases in our series, we experienced significant distal embolization in just 12, so less than 1%. In more than half of those 12 cases we were dealing with a chronic stenosis and heparin was administered, as per standard practice.

These challenging situations need to be managed rapidly as further thrombus is formed around the distal emboli making it harder to remove. Furthermore, patients become restless as distal embolization is associated with pain due to acute ischaemia and they struggle to tolerate the procedure as they find it difficult to remain still. Various methods have been suggested in the endovascular management of acute limb ischaemia following distal embolization

complicating lower limb intervention. These include catheter-directed thrombolysis (bolus or overnight), angioplasty, aspiration of the embolic material (manual, mechanical or electromechanical), or rheolytic thrombectomy.

Catheter-directed thrombolysis utilizes infusion of thrombolytic agents and can be limited by its effectiveness when the target is hard emboli. Furthermore, the result is not always immediate, there can be significant risk of bleeding—mainly stroke in octogenarians—and is not always effective at preventing surgical intervention. Schrijver et al. [4] demonstrated in their study, involving 28 patients who underwent catheter-directed thrombolysis for the treatment of acute upper extremity ischaemia, a

radiological success rate and clinical success rate of 61 and 68%, respectively, with an in-hospital amputation rate of 7%. In a separate and more recent study, Schrijver et al. [5] retrospectively analysed a larger cohort of 159 patients over 3 years who underwent catheter-directed thrombolysis for acute lower limb ischaemia in both native vessels and bypass grafts. The study demonstrated the risk associated with thrombolysis whereby major haemorrhagic complications occurred in 12% of native vessels and 7% of bypass grafts. Of the 12, 4% were major haemorrhagic strokes, 2% of which were fatal. Furthermore, long-term follow-up demonstrated poor outcomes with an amputation-free survival rate for native vessels of 76% at 1 year and 65% at 5 years. In our series, thrombolysis was used only in one case, in a 50-year-old patient, and was successful. In the cases that ended up with a stent, thrombolysis was not considered as a valid option given that the mean age was 77.1 years; therefore, the risk of stroke was high. In this group, a 49-year-old diabetic patient is also included; however, thrombolysis was not used in this case due to previous gastrointestinal bleed from a duodenal ulcer.

Aspiration techniques vary from using a basic syringe aspiration (that involves the use of a monorail catheter containing multiple side holes at the distal end with a syringe attached proximally for manual aspiration), advanced mechanical systems (such as Aspire© from Control Medical Technology mechanical allowing the user to maintain, increase or pulse the thrombectomy force) and electromechanical aspiration (Indigo© from Penumbra systems which utilizes an electrical pump providing a continuous vacuum allowing for hands-free aspiration and clot extraction) [6–9]. The processes can be limited to aspiration of small clots, and maintenance of access can be difficult. Monorail systems offer the possibility to maintain access; however, the aspiration effect is debatable. We used manual aspiration through an end-hole 5-Fr catheter in most of the cases because most of the operators were familiar with this manoeuvre. In few cases this system was successful and resolved or diminished the clot burden. In six cases aspiration was not enough and stent deployment was necessary to achieve an optimum result. In one of these cases the Indigo system was also used; however, it was also not successful.

Other centres used rheolytic thrombectomy (AngioJet, Boston Scientific Corporation) that performs breakdown of thrombus by a jet of saline directed to the thrombus [24]. The system is rather effective particularly when used in healthy vessels. However, in a hostile atherosclerotic territory the rheolytic process might lead to endothelial injury, severe haemorrhagic complications and inability to breakdown hard atherosclerotic embolic material. The system also is related to bradyarrhythmias and haemolysis and is linked to a significant cost [24, 25].

Spiliopoulos et al. [24] described the use of the rheolytic thrombectomy device for limb salvage in distal embolization that was combined with stenting. The stents, however, in this study were deployed mainly in the femoropopliteal axis, and the effect was synergistic not a “bail-out” of the thrombectomy device. Interestingly, in the above-mentioned study, a peripheral filter was also used during stent deployment to minimize distal embolization, a technique which we do not routinely use due to the high cost. The embolic protection devices (EPDs) are used to mitigate this risk when performing complex interventions; however, these are supported by small studies with small patient numbers and there is a considerable increase in the costs of the procedure. Furthermore, these devices do not provide a “complete” protection owing to intrinsic properties of the device profile [26, 27].

In our series the stent that was used was a balloon-expandable drug-eluting one. The advantage of using a balloon-expanding stent is that it helps to push and trap the embolic material, particularly the more solid atheroemboli, against the wall of the vessel facilitating vessel reperfusion. We did not experience further embolic events by “squeezing” the clot against the vessel wall, and there was no thrombus migration. In the early years, plain stents were used for BTK lesions; however, nowadays drug-eluting stents (DES) are nearly exclusively used by the vast majority of operators. Even though literature is not very extensive on this area, the main advantage of DES is that they significantly reduce the rate of restenosis as shown in bench and clinical studies, particularly those that are covered with everolimus, a very effective antiproliferative agent [11, 12, 28–32]. In our series the patency at 1 year of the stents was 100% and one of the stent was patent for more than 2 and half years, effect probably related to the presence of everolimus.

The cost of stents is also not so prohibitive any more. They might actually be more cost-effective if we consider that the cost of a drug-eluting stent in the UK market ranges between £250 and £350, whereas the cost of the rheolytic system catheter reaches £1200 without the added cost of the rental of the aspiration generator that is another £1000. A limitation may be the fact that an implantable device is used; however, the patients that we managed had very advanced disease anyway and these were extreme salvage attempts.

The technical success was 100%; however, there was an inevitable cost of losing one out of two vessels in two cases. Maintaining both vessels open would have been possible if bifurcational stents were more widely available “off the shelf” for the vessel below the knee. A 90-year-old patient passed away 9 days post-stenting due to gastrointestinal stromal tumour. We could make the argument on whether stent deployment was necessary in this case.

However, in the acute event of distal embolization the operator is keen in obtaining immediate reperfusion possible, particularly if the patient is complaining of acute pain. In one case amputation was performed for advanced osteomyelitis 1 month post-procedure. In this case SFA angioplasty was requested to improve stump healing and distal embolization was an unfortunate event. We could also argue in this case that stent deployment was not required given the already scheduled amputation; however, as previously mentioned, in the acute event the drive of the operator is mainly to alleviate patient's discomfort. In the four cases that were followed up, clinical success was 100% with ulcer healing and satisfactory long-term stent patency.

With stenting of the thrombus, there is always a risk of clot propagating distally. The risk is considered higher if angioplasty precedes stent deployment. Direct stenting in the femoropopliteal segment, however, appears effective in acute thrombus as demonstrated in a recently published series of 16 patients with long-term follow-up [33]. In our cases angioplasty was necessary to obtain immediate reperfusion and to define the length of the lesion that required stenting accepting the risk of distal embolization in an already blocked artery. Nevertheless, we did not experience any distal embolization in any of the cases post-angioplasty or below-the-knee stent deployment.

The multivariate regression analysis has confirmed that critical limb ischaemia is linked with the risk of stenting. This result is expected as the more advanced the disease is the more drastic reperfusion solutions will be required as the vascularization reserves are very limited. This element may also explain the relative high rate of failure of the conventional techniques. There is also a trend of the single-vessel run-off towards stent deployment, and this is also in a certain degree expected as if distal embolization occurs in a single vessel and conventional means fail, then the last resort will be stent deployment. The presence or not of an occluded SFA lesion does not appear to be related to the likelihood of stent placement after a distal embolic event, and this is completely justified by the fact that dramatic events may occur even when stenotic lesions are angioplastied.

## Conclusion

We may conclude that intraoperative distal embolization after femoropopliteal angioplasty may be managed with conventional means in most of the cases. When conventional methods fail, below-the-knee stents are a valid "bail-out" option offering very satisfactory immediate and long-term results even for patients with advanced peripheral vascular disease.

## Compliance with Ethical Standards

**Conflict of interest** None.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

**Informed Consent** Informed consent was obtained from all individual participants included in the study.

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