Infrapopliteal arterial recanalization: A true advance for limb salvage in diabetics

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Abstract The world is facing an epidemic of diabetes; consequently in the next years, critical limb ischemia (CLI) due to diabetic arterial disease, characterized by multiple and long occlusions of below-the-knee (BTK) vessels, will become a major issue for vascular operators. Revascularization is a key therapy in these patients as restoring adequate blood supply to the wound is essential for healing, thus avoiding major amputations. Endoluminal therapy for BTK arteries is now a key part of the vascular specialist armamentarium. Tibial artery endovascular approaches have been shown to achieve high limb salvage rates with low morbidity and mortality and endovascular interventions one should now consider to be the first line treatment in the majority of CLI patients, especially in those with associated medical comorbidities. To do so, the vascular specialist requires detailed knowledge of the BTK endovascular techniques and devices. The first step decision in tibial endovascular therapy is access. In this context, the antegrade ipsilateral approach is generally preferred. The next critical decision is the choice of the vessel(s) to be approached in order to achieve successful limb salvage. Obtaining pulsatile flow to the correct portion of the foot is the paramount for ulcer healing. As such, a good understanding of the current angiosome model should enhance clinical results. The devices used should be carefully selected and optimal choice of guide wire is also extremely important and should be based on the characteristics of the lesion (location, length, and stenosis/occlusion) together with the characteristics of the guide wire itself (tip load, stiffness, hydrophilic/hydrophobic coating, flexibility, torque transmission, trackability, and pushability). Passing through chronic total occlusions can be quite challenging. The vascular interventional radiologist needs therefore to master the techniques that have been recently described: anterograde approaches, including the drilling technique, the penetrating technique, the subintimal technique and the parallel technique; subintimal arterial flossing with anterograde-retrograde procedures (Safari); the pedal-plantar loop technique and revascularization through collateral fibular artery vessels.

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Critical ischemia and diabetes: the current situation

Chronic lower limb critical ischemia (CI) causes pain in patients when they are lying down, trophic problems and gangrene following a major deterioration in foot perfusion. It differs from acute ischemia because it is longstanding, present for more than 15 days and represents stages 4 to 6 of the Rutherford classification which has been accepted since the production of the TASC2 consensus document in 2007 [1]. Distal perfusion often becomes suddenly disrupted after many years of progression of unrecognized or even undiagnosed chronic disease. The natural history of this type of resting ischemia without “aggressive” treatment is extremely poor, as 1 year after nocturnal pain or ulceration have developed, 50% of patients are either dead or have been amputated [2–4]. It is estimated that one million amputations are carried out annually throughout the world, i.e., one every 30 seconds, half of which are performed first line with no prior diagnostic assessment [5]. Diabetes and its comorbidities, primarily neuropathy, are the predominant risk factor for developing CI [6,7]. The disease is part of a genuine pandemic with a prevalence of 4% in France, i.e., a figure consistent with the 4 million diabetic patients recognized; 7% of these suffer or have suffered from a foot wound once in their life (between 75,000 and 150,000 annually). More than 70% of healed diabetic wounds recur within 5 years, explaining the high frequency of amputations due to this disease or between 10 and 15,000/year, half of which are estimated to be avoidable as they have been preceded by unrecognized ulceration [8,9]. Not all diabetic wounds are ischemic but compared to neuropathic or mixed ulcers, they are the ones which carry the worst prognosis with a 5-year survival of 40% (65% for neuropathic ulcers) and an amputation rate of 28% (10% in the neuropathy group) [10].

Looking for obstructive arterial lesions is therefore a fundamental stage in the optimal management of a diabetic wound, guided by clinical examination and Doppler ultrasound. One of the fundamental features of diabetic CI is the predominance of diffuse and extensive disease along the subpopliteal tibial arteries either in isolation or concomitantly with proximal femoro-popliteal obstructive lesions [11–13]. Graziani et al. [14] showed through angiography that 417 diabetic patients with ischemic trophic disorders had 2893 lesions, 55% of which were obstructive. These involved the iliac arterial system in 1% of patients but were present in 74% of patients at the subpopliteal level, 66% of leg lesions were obstructive and 50% were over 10 cm in length. All three arterial systems were involved in 28% of patients whereas in 55%, at least one distal artery remained patent. The authors found a morphological increase in severity classification and noted that category 4 (2 obstructed arteries associated with multiple tibial-fibular and/or femoro-popliteal stenosis) was the most often recognized (36% of patients).

Calcifications are very common [15]; and are a combination of those which are relatively specific for diabetes (and chronic renal impairment), due to calcium deposition in the interstitium of media (Mönckeberg medial calcific sclerosis), which have long been the predominant lesion and spares the lumen of the artery and intimal classification which is characteristic of progression of atherosclerosis, gradually reducing the lumen of the artery. The assessment of calcifications, their severity and distribution is an important stage of the underlying thinking to decide on the method of endovascular recanalization, whether transluminal or extra-luminal, as described below.

Revascularization is the only solution which reperfuces the territory of the wound and allows it to heal. Until the end of the 1990s, the only revascularization technique for distal arteries was bypass surgery [16]. The endovascular options which developed for other anatomical areas were hindered at the time by materials which were inappropriate for the morphological features of subpopliteal obstructions. From the start of the millennium, however, the technical feasibility of endovascular methods with non-specific devices has been demonstrated clearly by the pioneers Dorros et al. and Söder et al. [17,18]. In later years, technological research directed towards creating dedicated angioplasty materials has logically been accompanied by an improvement in the technical success rate and this treatment method is being used for increasingly complex lesions [19–21]. As a result, endovascular revascularization has now become the first line choice to treat tibial obstruction in diabetic patients with CI [22–25]. This strategy is based on the superior perioperative safety of results compared to surgery. Results are at least equivalent in terms of efficacy, with a limb salvage rate at 1 year similar to that of surgery [26–28]. In 2008, Romiti et al. [29] made a meta-analysis including 30 studies on infrapopliteal vessel angioplasty (2557 cases) and found a primary patency rate of 48% at 3 years, secondary patency of 62%, limb salvage of 82% and a survival rate of 63%. No significant difference was found between the subgroups in which angioplasty was only used for the distal vessels and those combined with proximal treatment and no difference was also found between endo- and subintimal intentional angioplasty. Ferraresi et al. [30], in 2009, described 101 diabetic patients with CI treated by angioplasty for exclusively subpopliteal disease and found a limb salvage rate of 91% at 3 years, 9% of patients having died at 1 year, and a restenosis rate of 42% with only 3 patients undergoing a further angioplasty because of recurrence of the CI. In 2013, Park et al. [31] described a technical success rate of 93%, a limb salvage rate of 91% at 1 year and a primary patency rate of 75% in 63 patients in a clinical population similar to that of Ferraresi.

Healing is a phenomenon which is directly related to arterial flow and the basic approach as the ideal revascularization strategy therefore aims to maximize perfusion of the foot. Until recent years, the preferred endovascular approach was to seek direct anterograde blood flow in one of the three leg arterial systems (according to the principle that one patent vessel is better than nothing), generally defined as the artery which was most technically accessible to recanalization. A second chronological stage designed to optimize limb salvage aimed to achieve as complete revascularization as possible on the basis that 3 open vessels were better than 2, which were better than one! In 2010, Peregrin et al. [32] therefore showed that complete revascularization of the leg arterial system in diabetic patients with CI had a 1 year limb salvage rate of 56% if direct patency was not obtained in at least one vessel (0 vessels open) and 73%, 80% and 83% if one, 2 or 3 vessels became patent again.
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respectively. In 2005, Faglia et al. [33] carried out first line angioplasty in 993 diabetic patients with CI and found a major amputation rate of 2% at 2 years, with a 5-year limb salvage rate of 88%. He also found that angioplasty of tibial arteries (anterior and posterior) produced better results than when angioplasty was limited to the fibular artery.

A new relatively recent principle which has emerged is direct reperfusion of the artery supplying the wound territory (“wound-related artery” for English speaking authors) is based on the concept of the angiosome which is a composite, multi-tissue, anatomical unit (skin, subcutaneous tissue, fascia, muscles and bone) which is vascularized by a major vessel and represents a single skin territory (there are 40 of these in the human body). Taylor et al. [34,35] confirmed that 5 were located on the feet and ankle and corresponded to the three leg arteries: anterior tibial, posterior tibial and fibular (Fig. 1).

Attinger et al. [36] highlighted the importance of this concept in the initial work on plastic reconstruction surgery in the leg and Neville et al. [37] confirmed higher healing and limb salvage rates after distal bypass surgery to the artery supplying the ischemic angiosome. Alexandrescu et al. [38] used this model in 2008 to guide endovascular procedures at the different supra- and subinguinal levels in diabetic patients suffering from CI and achieved excellent results on a retrospective analysis in 98 patients (73% of patients were alive without amputation at 3 years). In 2011, the same group reported 3-year results in 213 patients with CI from a historic comparison, before (89 patients) and after (134 patients) introduction of the concept of “angiosome-guided” endovascular revascularization [39]. This appeared to be superior in the group in which revascularization was based on the concept of the angiosome (salvage rates: 89%/79%). In 2010, lida et al. [40] confirmed better results in 177 patients, (4-year limb salvage rate of 86%) when the angioplasty of blood vessels supplying the ischemic area (“direct” revascularization) had been achieved technically and to those in which this did not apply and when “indirect” revascularization involved one or more other vessels (salvage rate 69%).

This attractive concept should nevertheless be used with caution in “real life” as it has a number of absolute limitations: the published studies on the subject are all retrospective, invariably contain methodological bias and severe deep infected losses of tissue are rarely confined to a single angiosome, interruption of the connections between different arterial systems is often found in situations where forefoot amputation is justified, hence the need for the most complete possible revascularization carrying a hope of post-amputation healing [41]. Finally, direct revascularization is more or less useful depending on the quality of the collateral supply. Varela et al. [42] showed equivalent results in terms of healing and limb salvage for revascularization of the wound territory through the large collaterals which were still present and functional (plantar and fibular) and those which developed as a result of restoring flow in the corresponding angiosome artery.

In summary, the quest for complete and/or direct revascularization, whilst desirable, cannot be dogmatic and the endovascular procedure considered must be adapted for each patient in the light of “realistic” technical options and the patient’s overall clinical situation (Fig. 3).

Conventional leg blood vessel recanalization techniques in 2014

The initial crucial stage of endovascular revascularization is passing an angioplasty guide through the occluded area. The first line technique remains the anterograde transluminal crossing method, (through the lumen of the true artery which is now obstructed) which is recommended particularly

Figure 1. The 5 angiosomes of the feet and ankle correspond to the 3 leg arteries: posterior tibial (1: color orange), its collaterals and common terminal branches (2: color orange) and lateral (3: color yellow), anterior tibial arteries and its branches (4: color green), and fibular (5: color black).
Figure 2. a: severe critical ischemia of the right foot due to very tight stenosis at the origin of the anterior tibial artery and occlusion of the tibiofibular trunk before and after angioplasty; b: intraluminal recanalization of the posterior tibial artery followed by angioplasty of the anterior tibial stenosis; c: near complete healing at 4 months with restored patency of the anterior and posterior tibial arteries.

if extensive calcification is present in the vessel. Ipsilateral femoral arterial puncture, possibly ultrasound-guided, is the preferred approach for most operators as it optimizes guide-catheter couple manipulations [43]. A long 4F Desilet introducer (45 cm) is advanced to the lower popliteal artery, providing satisfactory support from the outset. The limitations of the approach are morbid obesity and the presence of proximal iliac or common or superficial femoral disease, in which case a retrograde contralateral femoral approach is performed using the "crossover" technique across the aortic bifurcation. Puncture is then more straightforward, carries less risk of iatrogenic bleeding but requires the use of long angioplasty devices which are certainly available (4F, 90 cm), although are slightly more difficult for the user. This trans- (or intra-) luminal recanalization via the guide are facilitated by concomitant use of a miniaturized "support" catheter (2.6F), which is reinforced (with a stainless steel mesh), may be angulated and is a genuine

Figure 3. Endoluminal recanalization of the anterior tibial artery by a 0.014 guide using the "drilling" technique before, during and post-angioplasty.
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The new arrival into the modern armamentarium, together with a dedicated guide of diameter of 0.014 or 0.018 inches, the manufacturing technology for which has been derived from an adaptation of the technology for recanalization of chronic coronary artery occlusions [44–47]. Each model of guide is based on a compromise between support from the catheter (the bore) and capacity to cross the occlusion, which is related to the rigidity of its distal tip. There is now a wide range of increasing rigidity guides available with polymer coatings which offer good capacity to cross the occlusion, some of which have a very high penetration potential using the principle of crossing the obstruction through the old true lumen which is now occluded and reaching the true lumen immediately beyond the obstruction (Fig. 2). Usually, the procedure is started with the “drilling” technique using 0.014 intermediate rigidity hydrophilic guides aiming to rotate fairly quickly with alternating clockwise and anticlockwise movements “pushing” gently: the direction of recanalization is dictated by the artery itself, probably because of the presence of areas of lower resistance in the occlusion which “attract” the sliding of the guide (Fig. 3).

If this method does not cross the occlusion and if the obstruction is not too long, the next step involves taking a second more rigid 0.014 guide (the first guide can be left in parallel in the subintimal space) or a 0.018 guide to attempt deliberate perforation maneuvers which involve more “forcing” of the guide. In this case, the path of the guide is dictated by the operator and no longer by the artery (Fig. 4).

Failure of these methods, (failures usually occur if the occlusion is very long), are due to massive calcification which deflect the guide from its intraluminal path, an attempt can then be made to cross the occlusion using a subintimal approach [48–50]. This can be carried out either using the same guide which spontaneously or intentionally has a characteristic loop at the entrance to the subintimal space or after changing materials and using a small J0.035 guide dedicated for this purpose. This technique is known as subintimal angioplasty and was designed by Bolia et al. [51]. It can also be considered first line when it is said to be “intentional”. This was for many years the only option before the development of miniaturized guides. If the obstruction is not calcified (Fig. 5), the estimated success rate is equivalent to that of intraluminal recanalization [52]. The technical failure rate due to the guide failing to re-enter the true lumen beyond the occlusion is around 20% when the artery contains little calcium or is uncalkified. The failure rate is increased in massive calcification and as a result, this method should be used by default in this anatomical situation. The small diameter of the lower leg vessels do not enable the “re-entry” commercial mechanical systems (such as “Outback-Cordis”, “Pioneer”, “Medtronic

**Figure 4.** Technical principles of the “drilling” (guide rotation) and “penetration” technique (the operator applies a degree of pushing force on the guide).  

**Figure 5.** Intentional subintimal angioplasty of the lower femoral popliteal and posterior tibial arteries with a dedicated 0.035 J guide.
catheter'' or ''Off-road-Boston'') to be used. Inflation of a balloon next to the assumed re-entry area or ''home-made'' fashioning of a diathermy cutting tip for a diagnostic catheter can be used to traumatically cross the dissection membrane and return subsequently into the true lumen (Fig. 6). The current technical success rate of intentional or unintentional intra- or extraluminal anterograde crossing of the occlusion is around 80% [53] (Fig. 7).

The next stage involves inflating an angioplasty catheter balloon, the profiles of which have also improved considerably.

Coaxial balloons which are compatible with 0.014 and 0.018 guides offer greater capacity to cross the occlusion than those belonging to the monorail systems and should be used in preference. They are available in a wide range of lengths (from 20 to 220 mm), with diameters of 1.5 to 4 mm; conical balloons whose diameter differs by 0.5 mm between the proximal and distal ends have been produced specifically for distal arteries; ''active'' balloons impregnated with paclitaxel are available in a wide range of lengths and diameters and appear to offer a better late patency rate than is obtained with uncoated balloons [54,55]; this technology in principle offers better future prospects than stents (auto-expanding Nitinol stents or expandable balloon on a steel or cobalt chrome stent) which are only justified in this site when suboptimal simple angioplasty results are acceptable (residual stenosis or dissection). Liistro et al. recently published a randomized study [55] which compared the effect of an active coated balloon with an uncoated balloon (Debate-BTK study) in 132 diabetic patients with CI and a long occlusion (14 cm) of the subpopliteal vessels and found a 1-year angiographic restenosis rate of 27% in the

Figure 6. A tip if re-entry fails after an attempt at subintimal angioplasty to create an intimal breach: using the ''sharpened'' end of a catheter and inflating an undersized balloon.

Figure 7. a: high occlusion of the anterior tibial artery and at several levels in the posterior tibial artery; b: subintimal recanalization of the posterior tibial artery; c: endoluminal recanalization of the anterior tibial artery with a 0.018 guide, introduction of a long balloon and immediate result.
coated active balloon group and 74% for the balloon, a 17% reocclusion value compared to 55% and a revascularization rate of the target lesion of 18% compared to 29%. These encouraging results have not, however, been confirmed in a more recent multicenter, randomized study (the as yet unpublished results of the In-Pact Deep study) which was stopped prematurely because of failure to meet the safety requirement and a considerably higher amputation rate was found in the active balloon group. It is not therefore possible at present to propose the first line use of this technology (or at least the type of active balloon used in the study in question) for subpopliteal angioplasty. There are no coated stents as yet dedicated to the lower limb vessels and the good results from their use compared to the uncoated stents seen in the occasional published studies in the literature have been obtained using coated coronary stents [56–58].

How to push back the boundaries and increase the feasibility of crossing the occlusion: the merits of retrograde arterial approaches

We have seen the technical failure rate using the traditional anterograde approach to be around 20% with modern devices although if the patient population is not carefully selected, this figure rises significantly (in a number of situations, these anterograde approaches which are attempted cannot recanalize the artery when chronic obstruction is present without a visible proximal stump). In order to minimize the risk of failure of endovascular revascularization, new solutions have become possible, mostly as a result of technological refinements of the materials in the form of retrograde access to the occluded vessel using different methods.

The dual or interventional "femoro-distal telepheric approach"

This procedure requires combining a conventional ipsilateral femoral approach with direct puncture of the leg vessel distal to the obstruction where it is still patent from rich collateral supply and which could not be reached anterogradely in order to cross the occlusion backwards. This is now proposed immediately after proximal approaches have failed, the introducer and guide being left in place [59–62]. The target artery is punctured under radioscopy control with a 21 G needle (4 to 7 cm), assisted by possible landmarking of calcifications and the use of radiological "road-mapping" mode, less commonly under ultrasound guidance. The puncture is usually made at the ankle and is relatively simple for the pedal artery, slightly more difficult for the retromalleolar portion of the posterior tibial artery, or higher on the fibular artery or even the anterior tibial [63–67] (Fig. 8). A 0.018 guide is then used to cross the upstream occlusion countercurrent, facilitated by the routine use of a relatively rigid 2.6 F support catheter (several commercial systems are available), and avoiding the use of an introducer, which are indeed contained in a 3F version but which can cause a degree of trauma. There are then two possibilities: either the 0.018 guide crosses the whole length of the tibial occlusion throughout the lumen and therefore reaches the true proximal popliteal lumen, or it passes through the subintimal space at some time during the navigation and does not end

Figure 8. a: failed anterograde recanalization of a fibular occlusion (the only artery visible) with subintimal navigation of the 0.018 guide; retrograde puncture of the fibular artery; b: retrograde catheterization of the 0.018 guide recovered in the 5 F anterograde catheter; c: result after anterograde inflation of a long balloon.
up in the true proximal lumen. In the first scenario, the solution is relatively simple and involves recovering the guide through the femoral introducer. A 6F angulated catheter or removable valve introducer can be used in order to allow catheterization of the lumen and removal with the retrograde guide. A home-made or commercial lasso system is another option to remove the guide from the patient in "telepheric" mode. Once the guide has been recovered, the balloon angioplasty is performed from a superior approach: dilatation material cannot be introduced from distally because of potential procedural problems avoiding damaging a tortuous fragile artery by inserting an introducer of inappropriate size or removing the balloon after inflation (hence the justification of the dual approach).

In the second scenario in which the retrograde guide and its support catheter pass into the subintimal space, the Safari technique (acronym for Subintimal arterial flossing with anterograde retrograde intervention — Flossing being the English term used to pass dental floss between the teeth to remove tartar!) is used. This was described in 2003 by Spinoza et al. [68] and involves recovering the 0.018 guide which is blocked in the subintimal space into the catheter coming from superiorly, also in this case. A microlasso system can be used to assist this and once this maneuver is successful, the complete unit is then removed in the femoral introducer and then angioplasty is then performed from above, using the "telepheric" technique. Failures are due to navigating both guides into the planes of the subintimal space too far away and incompatible with returning the retrograde guide into the proximal catheter. At the end of the procedure, hemostasis can be facilitated at the distal puncture site by low inflation pressure of a balloon against the puncture site although the manual pressure after removing the materials is usually sufficient and effective and local complications such as thrombosis are very rare.

The technical success of this approach using retrograde puncture after anterograde failure is estimated to be around 80%, [69,70] (Fig. 9). Even in 124 patients (12% of 1035 people treated with infrapopliteal angioplasty for CI between 2007 and 2010), in which anterograde recanalization failed, Gandini et al. [71] reported a technical success rate of 96% using this dual approach with a limb salvage rate of 83% at 6 months and a 10% mortality rate during clinical follow-up, with 26% repeat procedure and 16% amputation rates.

The "LOOP" technique

This technique can be used to recanalize a target artery via the plantar arcade or a sufficiently well-developed collateral supply:

The "pedal-plantar loop" technique [72] may be proposed when anterograde recanalization has failed and when it is possible to carry out a direct distal retrograde puncture. This involves navigating the guide-catheter couple through the plantar arcade between the plantar and dorsal

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Figure 9. a: proximal occlusion of the anterior tibial artery, the only artery visible, returning at the ankle: failure of recanalization from a superior approach; b: retrograde puncture of the anterior tibial artery at the junction of the pedal artery and attempted recovery of the guide into the 6F femoral Désilet catheter left in situ; c: meeting of the 2 guides and effective Safari technique; d: final result after anterograde balloon angioplasty.
Infrapopliteal and other femoral occlusion, missing guides, approach [73] through the new channel created by the retrograde guide, both leads usually size 0.014, travelling in the same ipsilateral femoral introducer. The main indication for this approach other than failure of an anterograde approach is its first line use when very distal interdigital disease is present, with the hope of improving perfusion of the forefoot by restoring missing connections in the toes and heels. In this specific situation, recanalization of the foot arteries, Manzi and Palena [73] described a technical success rate of 85% in 135 patients (10% of a population of patients treated via an endovascular approach for CI over a period of 2 years).

Transcollateral angioplasty: the recanalization is performed through a highly developed collateral artery which provides access to the occluded target vessel (Fig. 10). This is similar to the technique used during recanalization of a coronary occlusion and allows better targeting of the entrance to the occlusion and therefore shortens attempts to penetrate using specific guides [74].

“Extreme below-the-knee interventions”

If all of the techniques described above are unsuccessful or not possible, it is now technically possible to directly puncture the first metatarsal artery or even the plantar arcade and to undertake retrograde recanalization of the foot and lower leg arteries through this approach [75]. Palena and Manzi [76] reported a technical and clinical success rate of 85% at 6 months in 28 patients. Following local anesthesia and local administration of antispastic verapamil, the puncture is performed under radioangiography using a 21G needle, generally in the first metatarsal artery (25/28), and in this study, was associated with an increase in tcPo2 (12 mmHg preprocedure, compared to 49 mmHg at 6 months) with 71% of patients alive and not amputated at 6 months.

Conclusion

The range of technical endovascular revascularization possibilities for long tibial artery occlusions has recently increased considerably enabling anterograde endoluminal or even sub-intimal recanalization of occluded segments in 80% of cases by miniaturized 0.014 or 0.018 guides. If this approach fails, retrograde recanalization appears to be effective in almost 80% of situations, mostly using distal retrograde puncture and a dual femoro-distal “telepheric” approach, and less commonly by access through a collateral or by the principle of the “pedal-plantar loop” technique. Finally, even more distal punctures (of the first metatarsal artery!) are proposed by some as the ultimate fallback and appear to produce good results.

Figure 10. Distal occlusion of the two anterior and posterior tibial arteries, recanalization through the plantar arcade using the “Loop Technique” principle.

Figure 11. Distal anterior tibial artery angioplasty via the fibular artery.
Disclosure of interest

The authors declare that they have no conflicts of interest with this article.

References


