

Part X

Factors influencing results

Infrapopliteal Bypasses for Critical Lower Limb Ischemia. Influence of Surgical Experience on Outcome

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Critical limb ischemia is the usual indication to peripheral vascular reconstructive surgery; while surgical procedures for simple claudication are unwarranted, the onset of signs and symptoms of impending limb gangrene lead to expeditious operative planning and management.

When critical limb ischemia is present, the pattern of atherosclerotic disease is usually extended to several arterial segments. Pattern of occlusion may vary according to specific risk factors: diabetic patients usually have extensive involvement of the arteries of the leg, with relatively little disease in the more proximal segments; on the other side non-diabetic patients usually show involvement of the proximal femoro-popliteal arteries with or without involvement of the tibial vessels. Thus vascular reconstruction in the critical limb ischemia always involve the infrapopliteal arteries when the aorto-iliac vessels are not significantly affected.

Bypass to these segments has evolved in the year 80's and 90's and has reached remarkable results in term of short and long term patency and limb salvage. However clinical assessment, technical problems and postoperative management of these cases are complexes and need careful evaluation.

Clinical and invasive assessment

First step in the assessment of the patient with critical limb ischemia is a thorough evaluation of clinical history. It is important to distinguish ischemic pain from that caused by other reasons, such as neurological pathologies.

Physical examination helps in identifying the different pathologies: critical limb ischemia is usually associated with a variety of clinical signs, which can be present all together or as isolated phenomenon. Absent or clearly reduced pulses is the rule, however significant stenosis may be associated with apparently regular distal pulsatility. Colour of the skin, either pale or rubor for inflammation, reduced temperature, atrophy of muscles and skin annexes, presence of little or extensive areas of necrosis, edema, are all important signs which can indicate the necessity of a revascularization procedure. At this point identification of a regular ipsilateral or contralateral saphenous vein allows to delineate successive surgical planning.

Non-invasive assessment is mandatory in order to identify more precisely level and degree of arterial stenosis. Duplex imaging allows to exclude the presence of significant aorto-iliac disease which may jeopardize the destiny of distal revascularization. In this setting, measurement of ankle brachial indexes gives a quantitative assessment of vascular insufficiency. However diabetic and nephropatic patients with a long term history of hemodialysis may have heavily calcified arteries with altered compressibility and inconsistent pressure indexes.

Although recent papers in the literature have shown the possibility of determining surgical planning through non-invasive testing such as Duplex scanning and dedicated magnetic resonance imaging, the gold standard for infrapopliteal surgical planning remains contrast angiography in most vascular centres (1,2).

This exam must be carried on with particular care in this setting, since the diminished flow present in distal diseased arteries may alter the final result and lead to its misinterpretation. Particularly, care should be taken to inject contrast directly into the affected limb arteries and not only in the aorta, in order to insure adequate visualization of the distal circulation, and to include the ankle and feet arteries in the exam.

At this point surgical arterial reconstruction can be planned. Rarely is critical limb ischemia associated with isolated superficial femoral artery occlusion; usually multilevel disease is present and revascularization of the infrapopliteal arteries is needed. Alternatively serial obstructive lesions of the iliacs and the proximal femoral artery are detected: in these cases surgical planning should focus on aorto-iliac reconstruction as a first necessary step.

Key point of an infrapopliteal reconstruction is the appropriate indication: patient with extensive tissue necrosis which will not allow future limb functioning even in the presence of a reconstituted circulation should be considered for primary amputation. Similarly, patients with incapacity of independent mobilization or short life expectancy should not undergo complex vascular reconstructions. Although some authors have extended indication to patients with disabling claudication (3) most centers do not perform infrapopliteal revascularization other than for limb salvage. We believe that the latter is the most appropriate approach, and we currently attempt distal revascularization only in limb threatening ischemia.

Once appropriate indication has been given, type of vascular reconstruction should be planned. The sites for proximal inflow and distal outflow should be carefully selected. Segments of less severely diseased arteries with sufficient inflow and no significant proximal stenosis and good run-off should be chosen as proximal and distal anastomosis sites respectively.

Surgical technique

In situ or reversed saphenous vein bypass?

There is no doubt in the literature that the first choice in infrapopliteal reconstruction is the ipsilateral saphenous vein (4-7).

Although other autologous sources such as lesser saphenous, contralateral greater or lesser saphenous vein, and arm veins can be used, the first choice is the ipsilateral greater saphenous vein. Debate still persists about the way of utilizing it. Initially, the saphenous vein was used solely in the reversed fashion, and placed in the anatomical position, i.e. adjacent to the arteries to be revascularized (8,9).

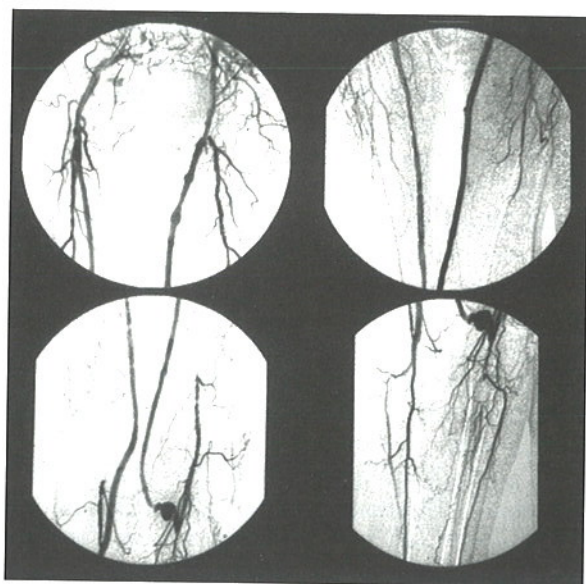


FIGURE 1

Control angiography in a patient with bilateral femoro-popliteal bypass. On the right side the bypass was performed with a reversed saphenous vein, while in the left side the vein was used in an "in situ" position, as one can see by the appearance of the residual valves enlarged sites. In the latter case the distal anastomosis is aneurysmal and needs surgical repair.



FIGURE 2

Control angiography of in situ saphenous vein bypass to the tibio-peroneal trunk. No residual valve leaflets nor anastomotic defect are present. The two residual arteriovenous communications (arrows) can be easily ligated under local anesthesia.

Subsequently the idea of using the vein "in situ", with disruption of the valves, took place (10). However the latter technique encountered initial skepticism until its definitive resuscitation in the 70's (11). Several technical details may in fact lead to failure of the in situ bypass: i.e. incomplete valve disruption, patency of large vein collaterals, tear of the intimal layer by the valvulotome (11). However other characteristics seem to favour its use over the traditional reversed saphenous: better anastomotic matching, particularly at the foot level, preservation of the vasa vasorum with no ischemic damage to the venous endothelium, no need for overdilation of the vein (12). Some authors have also suggested that small diameter saphenous vein perform better in the in situ fashion (12,13).

Others believe that reversed saphenous vein bypass is the method of choice because it can be performed in patients with no ipsilateral saphenous vein available and

TABLE I
Pros and cons of the reversed and the in situ saphenous vein techniques for infrapopliteal bypasses

	Pros	Cons
Reversed	Possible traslocation, with matching of specific anastomotic levels	Possible size mismatch at the anastomotic sites
	No technical failure due to incomplete valve disruption or branch ligation	Possible torsion or compression during tunnelling
In situ	Precise anastomotic matching	Possible technical error for incomplete valve disruption or branch ligation
	No endothelial ischemia	Impossibility of matching anastomotic levels other than these corresponding with vein location

in those in which arterial inflow or outflow does not match with the location fo the greater saphenous vein (14). Overall results for in situ and reversed saphenous vein bypasses are similar both short and long-term. Five-year patency rates were 69% in reversed femoro-tibial bypasses (14), and 73% with the in situ technique (15) (Fig1, 2).

It is important to note that the two techniques are not always interchangeable. The in situ technique is not performable in every situation and the reversed technique remains more versatile since source of the vein and position can be chosen more liberally. In other situations, such as long bypasses to the foot arteries, the in situ technique may be advantageous in term of vein positioning and anastomotic matching (Table I).

Overall, we believe that no definitive answer can be given on the choice between in situ and reversed saphenous vein bypass (16,17). Each surgeon should use his more familiar approach, since the learning curve of both techniques is rather long, and attention to details and experience play a crucial role in determing short and long term patency. However no indiscriminate adherence to one of the two methods should be maintained and a flexible approach will lead to best vein bypass performance.

Is there a role for prosthetic graft infrapopliteal bypass?

When both ipsilateral and contralateral saphenous veins are unavaible, other sources of autogenous vein should be searched for. Lesser saphenous and brachial veins can be alternatively used; however their caliber and structure is insufficient for adequate grafting in most cases (4,7).

Prosthetic material allows to perform relatively quick, simple distal bypass with patency rates significantly inferior than those of autogenous material.

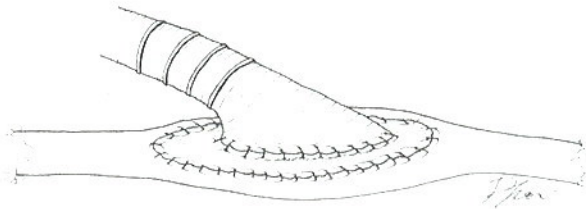
Particularly, mid and long term results are disappointing, and many authors have questioned the benefit offered by such an approach. Calligaro et al. reported a 2-year patency rate of 26% in PTFE infrapopliteal bypasses compared with 23% of lesser saphenous vein and 46% of arm vein bypasses in a series of 96 cases in which the greater saphenous vein was unavalable (18). This difference was not statistically different. Since other series have confirmed these disappointing long-term results, some authors have proposed primary amputation as a first choice option in patients

with critical limb ischemia and unavailable autogenous veins (19-21).

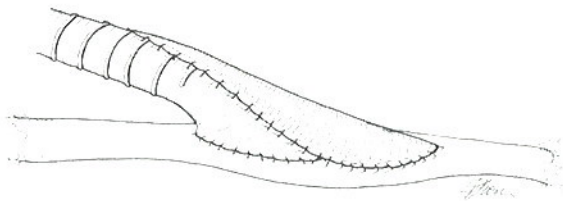
The rationale for primary amputation in these cases is to avoid ripetitive surgical procedure to a debilitated patient with few chance of preserving his limb. It is further supported by the fact that a primary amputation may be carried on at a more distal level compared with an amputation performed after a failed bypass, where thrombosis of collateral vessels occurs (21). Moreover 33% of these patients will die within 3 years (22).

However one should consider that proper indication for infrapopliteal revascularization is limb salvage: under these circumstances prosthetics are a reasonable choice when saphenous veins are unavailable. Some authors favour the option of arm vein as an alternative autologous material, while others have argued that these veins are often inadequate for distal bypasses and their harvesting is tedious and too invasive for the arms of the elderly patient (23).

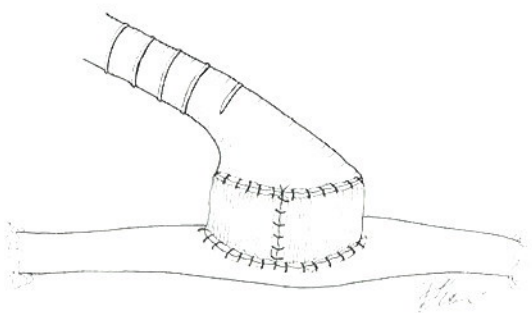
Long-term patency remains however poor in prosthetic femoro-distal bypasses, therefore many technical details have been reviewed and added in order to allow satisfactory results. The construction of an artero-venous fistula at the distal anastomosis seems to ameliorate patency of prosthetic bypass grafts, with 3-year patency up to 62% and limb salvage rate to 77% (24-26). Others have advocated the use of venous interposition at the distal anastomosis: the vein may be tailored as a cuff (27) a patch (28) or a boot-shaped reservoir (29) (Fig 3,4,5). The rationale for the use of the interposition vein is to reduce the compliance mismatch between the prosthetic graft and the artery (24, 27-29). With these adjunct, infrapopliteal prosthetic bypass may achieve 2-year patencies in the order of 50%, with limb salvage up to 90% (19). Also, the process of intimal hyperplasia is better tolerated when the distal anastomosis is widened by the presence of a segment of vein

**FIGURE 3**

Artist's interpretation of the "Linton patch".
A venous patch is placed to enlarge the arterial site of the distal anastomosis, and the prosthetic graft is then anastomose to it.

**FIGURE 4**

Artist's interpretation of the "Taylor patch".
The venous patch is sutured over the "toe" of the anastomosis, in order to elongate and enlarge it.

**FIGURE 5**

Artist's interpretation of the "Miller collar", which is constructed with a segment of vein and interponed between graft and artery.

(30-31) (Fig 6). It is important to note that when the graft fails, the venous patch or collar remains patent, thus preserving the distal vessels (19, 32).

The use of a prosthetic graft is also encouraged for secondary bypasses when the primary procedure has

failed. Under these circumstances one can achieve a secondary patency rate of 55% at 4 years, with a limb salvage rate of 74% (33).

Given these data and the fact that amputation leads to a high rate of nonambulatory patients, with psychological and physical deterioration (34) we believe that the use of prosthetic grafts in the infrapopliteal position is indicated in patients with critical limb ischemia and unavailable autogenous tissue. Only patients with extensive tissue loss at the extremity, with no expectation of functional recovery of the limb, or those with severe infection of the necrotic tissue should undergo primary amputation. Technical details are crucial for acceptable long term patencies.

Endovascular techniques: present and future

Attempts to revascularize obstructed arteries of the lower limb with methods different from bypass grafting have been proposed since 1947, when Dos Santos performed the first superficial femoral artery endarterectomy (35).

Subsequently, several minimally invasive technique that recalled the basic principles of that technique have been developed and tested. Percutaneous transluminal angioplasty, laser assisted balloon angioplasty and different atherectomy devices were used in different clinical settings by a variety of authors, however the results have been disappointing, with 3-year patency rates of balloon angioplasty around 60%. The introduction of directional atherectomy did not allow to ameliorate these patencies (36-41).

Reason for mid and long-term failure were thought to be the excessive length of the endarterectomized arterial segment, with subsequent development of intimal hyperplasia. Thus a different approach has been developed. With an extensive "closed" endarterectomy of the superficial femoral artery, early and late (5-year) patencies of 89% and 61% respectively were achieved (42). This technique is performed through a double access, proximal at the common femoral and distal at the popliteal arteries, and subsequent superficial femoral artery endarterectomy. The distal end of the endarterectomized segment is secured with tacking sutures (42).

Based on these results, Ho et al. developed a remote endarterectomy procedure, with a single proximal access and fixation of the distal end of the endarterectomy through balloon/stent technology. With this technique, a 3-year patency of 61.4% was achieved (43,44).

Thus, it appears that modern amelioration of endovascular techniques and material may enlarge the spectrum of indications to arterial districts traditionally believed to be exclusively treatable with conventional surgical procedures. In this view, use of a combination of tradi-

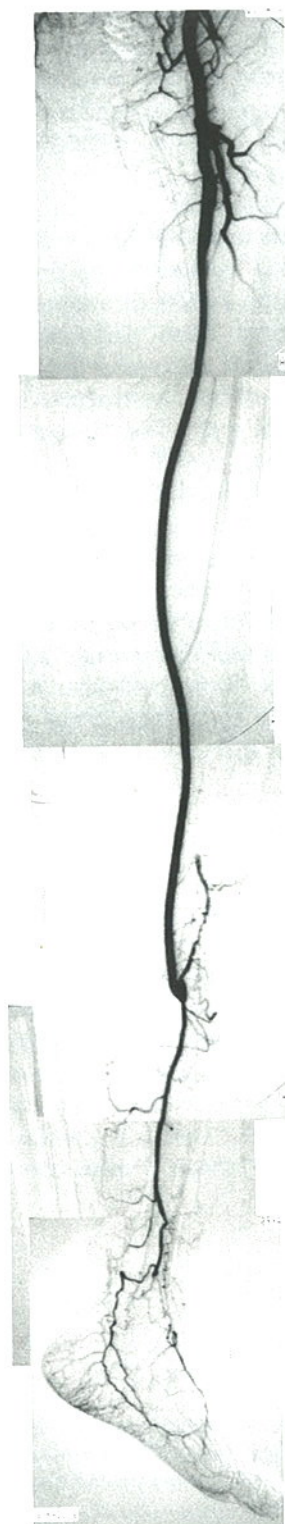


FIGURE 6

Control angiography of a PTFE bypass graft with a distal "Linton's patch" performed in a 82 year-old lady, with tissue loss of the toes and bilateral varicose veins.

tional angioplasty procedures and recent endografting technique may lead to successful treatment also of infrapopliteal occlusive disease. With this technique 1-year primary patency rate was 73.1% in 55 patients treated in Belgium (45).

Therefore we have started to treat a selected number of patients by performing balloon angioplasty of the distal superficial femoral and the popliteal artery and inserting an endograft over the dilated segment, in order to prevent intimal hyperplasia restenosis. Although the obstructive lesion is often above the knee joint, conventional bypass grafting would require an approach to the distal popliteal artery or to its tibial and peroneal branches. Our rate of technical success is currently 100% in 6 patients treated with angioplasty and subsequent insertion of an (hemobahn) endograft. One distal tibial embolization occurred, which was treated with loco-regional fibrinolysis and subsequent recanalization of the artery. Mid and long-term results are to be evaluated to determine the role of this procedure.

However, only selected cases can be treated by means of this technique, due to the presence of heavy calcification, long occlusions, diseased distal popliteal or tibial vessels. Moreover, mid and long-term patencies of this method are unknown.

Continuous progression in endovascular material let us believe that the armamentarium of the contemporary vascular surgeon must contemplate also unconventional endoluminal techniques. Current available data are restricted in the great majority of cases to occlusive disease of the superficial femoral or the proximal popliteal artery; moreover indication for revascularization often include claudication rather than rest pain or tissue necrosis. Thus, despite necessity of continuous effort and research in endovascular methods for the treatment of infrapopliteal obstructive disease, conventional surgical revascularization continues to be the only reliable method to treat critical leg ischemia caused by infrapopliteal disease.

Results

Our indication for infrapopliteal revascularization is restricted to limb threatening ischemia. In-situ saphenous vein is preferentially employed, and valvulotomy is usually performed under angioscopic control, with a modified Mill's valvulotome.

Twohundredsixtysix "in situ" bypasses have been performed to date with a cumulative primary assisted patency of 78%. This result reflects the overall performance of the in situ technique independently from the distal anastomotic site; infact we were unable to demonstrate any significant difference according to length of bypass and site of distal anastomosis. Surprisingly enough patency of bypass carried to the

popliteal artery or the proximal portion of the tibio-peroneal trunk were slightly worse than that of similar bypasses carried to the tibial arteries or to the arteries of the foot. We have postulated that the angulation of the vein at the knee joint in the "proximal" bypasses may adversely affect the better run-off of these arteries. In this regard we now preferentially reverse the saphenous vein and place it in the anatomic position when a bypass to the popliteal artery is needed.

Although limited, our experience with prosthetic bypasses to the tibial arteries have been encouraging. By using a vein cuff for performing the distal anastomosis, the primary patency at 30 days has been 85 % in a series of 21 procedures. Mid and long-term patency of these procedures is still an issue; however, if one consider that the alternative is a primary amputation, and that limb salvage can be achieved even with short term patency of the bypass, prosthetic rivascularization is justifiable for infrapopliteal disease when autologous vein is lacking.

Postoperative medical treatment

The challenging surgical revascularization, when successful, is not the final procedure in the treatment of the patient with critical limb ischemia; rather one can say that the real therapy for preserving the limb starts from it. As a matter of fact, several issues need to be addressed in the postoperative care of the patients.

First, adequate strategies for tissue necrosis debridement and care should be developed. Humid gangrenous lesions should be closely observed and medicated until a clear demarcation border from the adjacent healthy tissue develops. This process is usually favored by topical and systemic antimicrobial drugs: specific antibiotics and medication with iodine solutions are usually employed.

Once a clear separation border between healthy and necrotic tissue is obtained and the gangrene has dried up, removal of the affected zone can be safely performed. Dry gangrenous toes can be either amputated or left in place with adequate medication until their spontaneous detachment.

In the first year after operation, approximately 30 to 40% of grafts will occlude despite absence of technical defects (46). Although few prospective randomized studies on the effects of antiplatelets and anticoagulant drugs have been performed in this setting, recent meta-analysis showed a benefit associated with the use of these drugs, particularly in patients with a prosthetic bypass graft. The reason for better protection from occlusion in PTFE compared with vein grafts is supposed to rely on the antithrombotic action of the endothelial cells present in the vein. Oral anticoagulants associated with antiplatelets drugs are more effective than antiplatelet therapy alone in preventing late occlusion of femoro-popliteal grafts. An INR ratio between 3 and 4.5 should be maintained in these patients. We usually follow these guidelines in all cases with a prosthetic bypass to infrapopliteal graft, unless contraindicated.

Conclusions

Infrapopliteal bypasses for critical limb ischemia is one of the challenge for the contemporary vascular surgeon: although recent progresses of endovascular techniques may be of great utility for associate integrative procedures, the performance of distal bypasses is still dependent on surgical skill and appropriate indication and treatment planning. Meticulous technique, choice of adequate cases and graft material, postoperative care and surveillance are the main-steps on which limb salvage is based upon.

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