Part VI

Interventional treatments

Endovascular and Other Minimally Invasive Treatment Modalities for Aorto Occlusive Diseases

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During the past three to four decades, the treatment of aorto-iliac occlusive disease has not only been a surgical one. After Dotter and Judkins (1) introduced percutaneous transluminal angioplasty (PTA) in 1964, balloon angioplasty became a feasible treatment for small and medium sized occluded or stenotic arteries. It was not until the early eighties, with the introduction of larger balloons that stenoses in major vessels, like the abdominal aorta, could also be treated (2,3). Refinement of the angioplasty technique with so called kissing balloons made it possible to treat stenotic lesions at the aortic bifurcation. Finally, the introduction of stents made percutaneous transluminal angioplasty a more serious opponent to surgical bypass, even for the abdominal aorta. In addition to primary stent placement the possibility to treat early or late restenosis following balloon angioplasty by re-PTA with stent placement replaces or at least postpones large surgical procedures. In patients with ulcerated aorto-iliac lesions, stent placement removes the fear of embolization associated with balloon angioplasty alone.

This chapter reviews the current state of art in endovascular treatment of occlusive aorto-iliac diseases. Furthermore, the minimally invasive technique of (remote) endarterectomy, in both iliac and aorto-iliac stenotic diseases, will be discussed.

Exiuded are those occlusions due to chronic dissection and obstructive disease as a consequence of arteritis or fibromuscular dysplasia. Also stenotic lesions of the iliac arteries as a consequence of repetitive strain, as in the case of professional cyclists, are beyond the scope of this chapter.

Endovascular treatment of the stenotic infrarenal aorta

Pathophysiology

The infrarenal abdominal aorta and the iliac arteries are the most common sites of atherosclerosis in patients suffering from ischaemic disease. Localized stenosis of the infrarenal aorta, however, is relatively infrequent. Most affected are young patients, in particular women, who are heavy smokers and who have a relatively high frequency of abnormal blood lipid levels (4,5). In several studies a relation between localized aortic stenosis and a hypoplastic aorto-iliac syndrome is suggested. Sproul and Pinto (6) consider that the abdominal aortic stenosis found in the fourth decade or later in female smokers is a result of superimposition of acquired atherosclerosis, secondary to smoking, upon a hypoplastic lower aortic segment. Another theory is the combination of a high iliac bifurcation with a hypoplastic aorta in young women (7). Clinically, haemodynamically significant stenosis of the lower infrarenal aorta manifests as bilateral claudication. Less common, lower-limb atheroembolic events are the first symptoms of ulcerative stenotic aorta lesions. Traditionally endarterectomy was the treatment of choice for localized aortic stenosis.

Endarterectomy of the aorto-iliac conduit can also give durable results for patients with localized non-aneurysmal disease of the aorto-iliac region provided that the stenosis does not extend to the external iliac arteries. In the literature, acceptable results have been published for localized endarterectomy of the abominal aorta. An eleven year cumulative patency rate of 86% (8) and an operative mortality rate of about 3% is reported. However, these studies are retrospective and, do not follow current standards for analysis. Also important is the fact that most failures of endarterectomy are associated with small, hypoplastic central arteries (men and women) and this is one of the at risk groups.

Methods of treatment

Since the early 1980s successful PTA of the infrarenal abdominal aorta has been reported. Currently, PTA of localized aortic stenosis is performed under local anesthesia via the femoral approach using the Seldinger technique. In former days, two 7 or 8 mm dilatation balloons were introduced via both femoral arteries through 7 Fr sheaths. Dilatation of the lower abdominal aorta could only be performed by the simultaneously application of two, or even three balloons in the lower aorta segment. The third balloon had to be introduced through one of the brachial arteries. Nowadays, the development of larger balloons, makes it possible to introduce one single 10 to 15 mm balloon via the same 7 Fr sheath. The larger the balloon, the lower the inflation pressure necessary to get the same radial force. The 10 to 15 mm balloons used for PTA of the aorta have a normal dilatation pressure of 4 atmosphere

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(atm), whereas the rated burst pressure is up to 6 atm. Usually there is no need to inflate the balloons with more than 3 to 4 atm for one minute. The so called kissing-balloon technique is indicated for stenoses near the aortic bifurcation. Two balloons, positioned in the origin of the common iliac arteries, are inflated simultaneously to prevent compression of the contralateral artery. It is important not to use high dilatation pressures as rupture of the aorta is to be avoided. Clinically, discomfort of overstretching the aorta manifests itself in lower back or abdominal pain.

The authors prefer transluminal angioplasty of the aorta using non-compliant balloons. Non-compliant balloons as opposed to compliant ones, ask more of the manual skills of the radiologists, but pass their radial forces better on to the stenotic lesion(s).

Results and handling of complications

In the literature a PTA procedure is called technically successful when the residual stenosis after angioplasty is less than 30-50% of the diameter of the normal aortic segment and/or the systolic pressure gradient over the dilated segment is less than 10 mmHg without administration of vasodilators. Clinical improvement means a symptomatic improvement of at least one Fontaine class (9). An increase of ankle/brachial index more than 0.10-0.15 is defined as a haemodynamic improvement.

Contrary to balloon angioplasty of the iliofemoral section only a few publications exist of PTA of localized infrarenal aorta stenosis. Recently, the authors reported their own mid-term results of 38 patients for localized occlusion of the infrarenal aorta (10). Initial clinical and angiographic success was achieved in 94% of the patients, whith no major complications seen. In figure 1 a successful example of PTA of the aorta is shown. Minor complications consisted of iliac dissection (n=2) which could be treated by PTA with additional stent placement. In general, most of the dissections induced by angioplasty can be treated by additional stent placement. PTA induced peripheral emboli were not seen. In two patients balloon angioplasty was not possible due to technical problems and aortic bifurcation bypass grafts had to be placed. At the mean follow up of approximately three years, 7 out of 38 patients developed more than 50% restenosis. Five of these seven patients were asymptomatic and all could be successfully treated by a second PTA. Comparible results have been reported previously (11,12). In case of dilatation induced rupture of the aorta, it is most important not to remove the introduced balloon(s) and/or guide wires. There is no better temporary solution to minimize or stop the bleeding than an inflated balloon at the site of rupture. In recent days, dilatation induced ruptures can be treated quite easily by the additional placement of covered stents (e.g. Wallgraft®, Jostent®).

When the rupture cannot be treated by the placement of covered stents and surgery is necessary, it is important to keep the balloon(s) inflated at the site of rupture. Attendant guide wires can also be used to introduce occlusion balloons transfemorally, during surgical exposure to stop backbleeding from the iliac arteries.

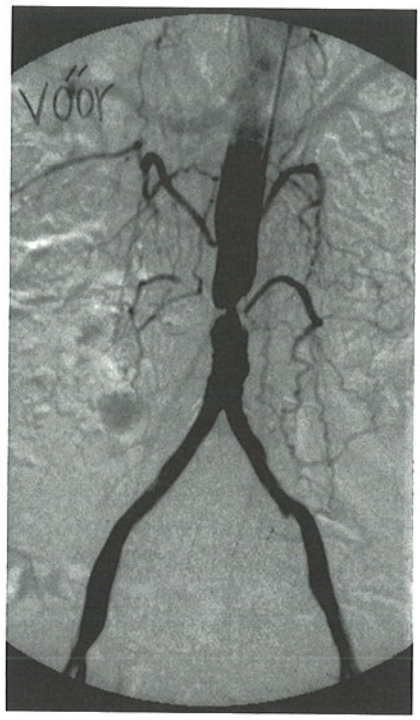

FIGURE 1a

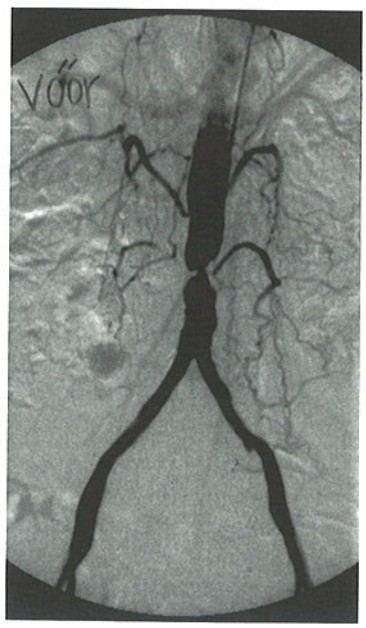

FIGURE 1b

Severe stenosis of the lower abdominal aorta before (figure Ia) and after (figure Ib) balloon angioplasty.

It is possible for a minor arterial wall perforation, for example caused by a sharp calcified plaque, to be missed during the procedure. Because of this, a pseudoaneurysm can develop. It is the authors' experience that these pseudoaneurysms can also be safely excluded by additional placement of covered stents. In figure 2 the successful treatment of a mycotic aneurysm of the common iliac artery is demonstrated with the placement of a covered Wallgraft®.

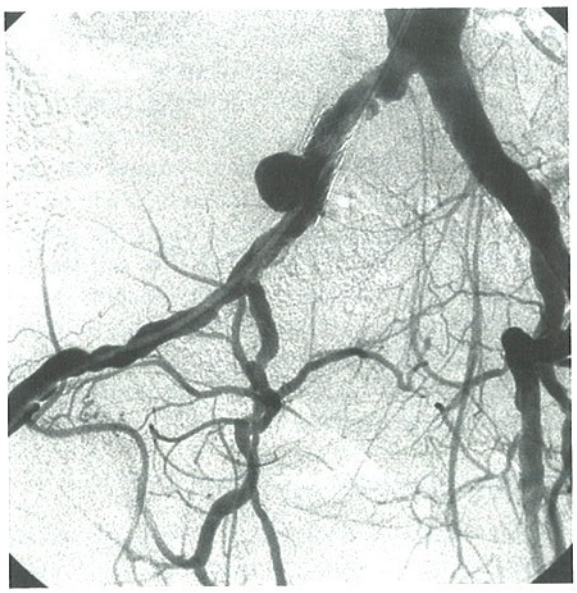

FIGURE 2a

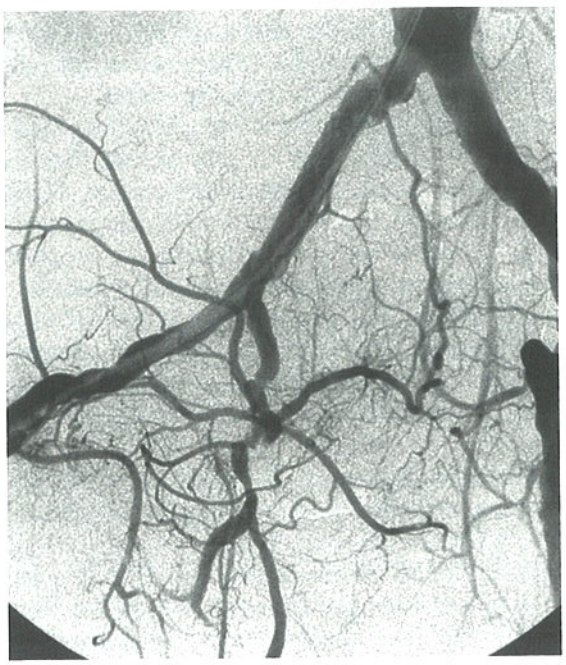

FIGURE 2b

Three months after placement of a Wall stent in the right common iliac artery a mycotic aneurysm (figure 2a) is successfully treated by additional placement of a covered Wallgraft® (figure 2b).

Whether and when balloon angioplasty should be combined with stent placement in the infrarenal aorta is not fully clear. In particular cases, additional stent placement in the iliac arteries can provide better haemodynamic results than can be expected from the abdominal aorta. So far, no randomized controlled study has been done to elucidate the criteria for additional stent placement in the aorta. Part of the problem is the discrepancy between clinical and angiographic findings. Haemodynamic failure does not always mean bad clinical outcome and vice versa (13). Recently Therasse et al. (14) found no difference in the long-term restenosis rate after PTA alone and aortic stent placement. There were no major complications associated with aortic stent placement. The unexpected increased risk of mid- and long-term clinical failure of patients who underwent additional stent placement can be explained by the fact that stent insertion is done in significantly smaller aortas.

Endovascular treatment of the stenotic iliac arteries

Epidemiology and classification

One of the most affected regions in peripheral arterial disease (PAD) is the iliac region. The prevalence of PAD depends on the criteria used for diagnosis. The most frequently used criterion is intermittent claudication which has a prevalence of about 5% in people approximately 60 years of age. In the age brackets of 30 to 60 years peripheral atherosclerosis appears 1 to 2 times more often in men than in women. Above 60 years the annual incidence of PAD is almost equal for both sexes (5,5 to 6 per 1000) (15). One fourth of PAD patients who survive for several years will show progression of ischemia and approximately four percent require amputation. Taking into account the strong increase of the worldwide ageing population peripheral atherosclerosis will have important socio-economic implications.

Specific complaints due to stenosis or occlusion of the iliac arteries are buttock claudication and erectile dysfunction in men. At physical examination the femoral pulse will be weak or absent and bruits can be heard. Based on extension and configuration, the stenotic or occluded iliac segment can be divided into four categories (9). Stenoses in category 1 (less than 3 cm in length and concentric and noncalcified) and 2 (3 to 5 cm in length or, calcified / eccentric and less than 3 cm in length) are suitable for balloon angioplasty, whereas ste-

noses of category 3 (length 5 to 10 cm or occlusion less than 5 cm) are a real challenge for the intervention radiologists. In general, category 4 lesions (stenoses greater than 10 cm in length, occlusions greater than 5 cm in length or extensive bilateral aorto-iliac atherosclerotic disease) are not suitable for endovascular treatment.

Methods of treatment

Since the mid eighties, percutaneous transluminal dilatation has become an accepted important technique in the management of patients with iliac occlusive disease. During these years the procedure has not essentially changed. In brief, the main steps of the technique include:

1) passing of the occluded or stenotic iliac segment with a guide wire and a 5-7 Fr catheter;
2) balloon angioplasty of the affected segment with a balloon diameter which matches the most normal appearing iliac segment near the site of the stenosis. For diameter measurements a calibrated angiography or a three-dimensional reconstruction angriography can be used. In some cases so called eye-balling of the interventional radiologist will be enough;
3) if necessary subsequent placement of a stent.

Mostly the above mentioned procedures are performed under local anesthesia. Three general types of intravascular stents have been developed: balloon expandable (e.g. Palmaz®, Corinthian®), self-expanding (e.g. Wallstent®) and thermal memory (e.g. Memotherm®) stents. In general, the stiffness of the stent is related to the metal used, the length of the stent, strut caliber, and the ratio between the compressed and expanded diameter (16). In in-vitro studies, the Palmaz® stent proved to be three times more rigid than the Wallstent®, with a higher radial force (17). Besides the radial resistance or hoop strength (the ability of a stent to withstand the radial compressive forces) there are two more key characteristics; the flexibility and pushability, characteristics important, for example, in tortuous vessels; and the radiopacity, which plays a crucial role in controlling appropriate positioning and deployment of the stent.

All available stents have an expansion ratio of approximately 6:1. More variable is the foreshorting; this ranges from about 40% for self-expanding stents to less than 10% for nitinol stents, which makes self-expanding stents more difficult to position precisely. Because of the rigidity of the balloon expandable stent and its greater radial force, Palmaz® stents are frequently used for PTA of the lower abdominal aorta and the common iliac arteries. In areas where asymmetrical and abnormally high external forces on the stent must be expected, balloon-expandable stents should be avoided anyway.

As the words convey, balloon expandable stents have to be dilatated with matched dilatation balloons. The self-expanding and thermal memory stents have both longitudinal and radial flexibility, which make them suitable for placement at areas of flexure like the external iliac or common femoral arteries and for the so-called cross-over technique. To treat stenotic or ulcerative lesions in the aortic bifurcation two balloons should be positioned, each in the proximal common iliac artery. The balloons have to be inflated simultaneously to avoid complications at the contralateral common iliac artery.

To minimize the formation of thrombus in the stents placed or at the PTA induced micro- of macroscopically damaged intima, all patients should receive antiplatelet inhibitors or anticoagulant medication. It is known that the re-endotheliaziation process of correctly expanded stents lasts at least eight weeks (18). The authors prefer a combination of Ascal and Persantin 25/200 mg twice daily, beginning the day before treatment and lasting at least three months. Because of multi level stenotic peripheral disease, most patients continue aspirin medication for the rest of their life.

Patients and evaluation of results

Quite a number of studies have been published about the endovascular treatment of non-aneurysmal disease. Because of many variables like a) the type of stent used, b) the variance in lesion: stenosis or occlusion, c) the location of the lesion: common iliac or external iliac artery, d) patient variables, e) the definition of clinical or hemodynamic success, f) the experience of the radiologists, it is rather difficult to compare results.

Another important factor is the evaluation of the outcome of PTA. Tetteroo et al. (19) proved that angiography is inadequate for the determination of angioplasty results, with a sensitivity of 45% and a specificity of 63%. The same authors also studied the variability of intraarterial pressure measurements and concluded that the variability has little consequence in the detection of hemodynamically significant stenosis after angioplasty. This makes intraarterial pressure measurements the standard of reference for the evaluation of endovascular treatment.

Non-invasive follow up of treated or untreated stenosis in the aorto-iliac segments can best be done with the use of Duplex scanning (20).

Contrary to all above mentioned variables, several important outcomes can be extracted. In the Toronto series (21) 667 iliac percutaneous transluminal angioplasties were studied thoroughly. Initial success rate (improvement of both clinical grade and non-invasive vasculator laboratory measurements) was well over 90%. Late success rates were 75.2 ± 1.8% at 1 year and 53.4 ± 2.7% at 5 years. These results are comparable to other studies (22). Several variables were found

to be associated with the success of PTA using univariate analysis.

Common iliac balloon angioplasty results were better than external iliac alone or a combination of the two (58.8% success at 5 years compared to 46.1%). Run off score is also an important factor for successful angioplasty (good run off, 57% five years success rate versus poor run off, 44.7%).

Angioplasty clinical success rate in consideration of limb salvage is lower compared to disabling intermittent claudication (53.8% versus 48.7% at 5 years). The most explicit discrepancy in success rate was found in the severity of the lesion. At 1 year follow up, PTA results of occluded iliac segments were significantly worse compared to stenotic ones (48.3% versus 77.4%). As a consequence, the additional use of stents in the endovascular treatment of iliac occlusive disease has grown rapidly in recent years. Figure 3 shows a successful recanalisation of a long occluded common iliac segment.

In most studies, the technical success rate of stent placement is rather good. Initial success rates are up to 95 to 98% with a four year patency of about 80% (23). Additional stent placement improves hemodynamics in iliac arteries. Following stenting the mean pressure gradient across the treated iliac area is reduced to an average of 2 mmHg (24) which is less than PTA alone. Also, the rise in mean ankle-brachial indeces is higher after additional stenting. Both findings could improve clinical outcome after endovascular treatment of peripheral occlusive disease, but were not studied in a randomized way in these publications. In our opinion only one randomized comparison of stenting versus PTA for peripheral occlusive disease has been performed, but unfortunately has not been published. In only an abstract (25), Richter et al. find reason to conclude that clinical outcomes with stent placement are more long-lasting when compared to angioplasty alone (cumulative five years clinical success rate of 93% versus 70%). However, the authors did not define clinical success.

In another randomized study, on behalf of the Dutch Iliac Stent Trial Study Group (DIST), Tetteroo et al. (26) compared the mid-term clinical results of primary stent placement versus primary angioplasty followed by selective stent placement in patients with iliac occlusive disease. At two year follow up, the authors could not prove substantial differences in technical and clinical outcomes of the two treatment strategies. However, the DIST study made clear that primary stent placement has to be performed in cases of recanalisation and when a significant hemodynamic stenosis persists after balloon angioplasty. Up to 90% of the studied patients were treated for intermittent claudication with a stenotic iliac lesion. Therefore the results of the study cannot be extended to patients with critical ischemia.

Complications are roughly the same as mentioned in the aortic section and consist of minor problems like hematoma at the puncture site, vasovagal collapse and peripheral embolism. Major complications include dissection or acute occlusion of the treated arterial segment, arterial-wall perforation and the development of pseudoaneurysms.

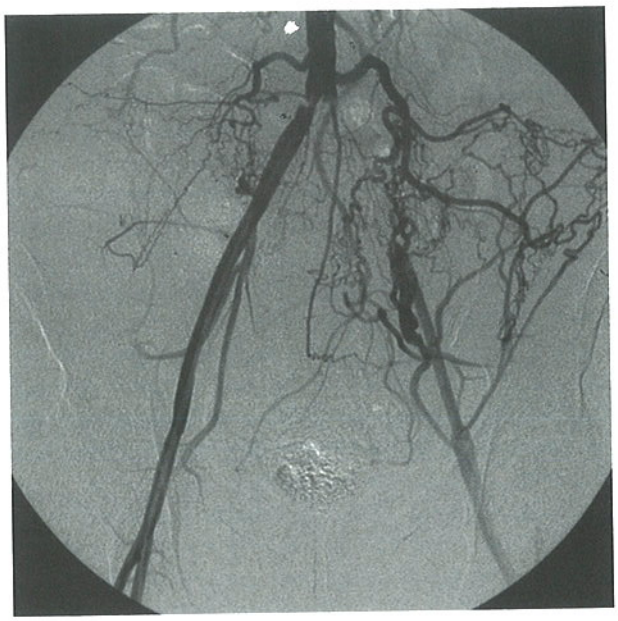

FIGURE 3a

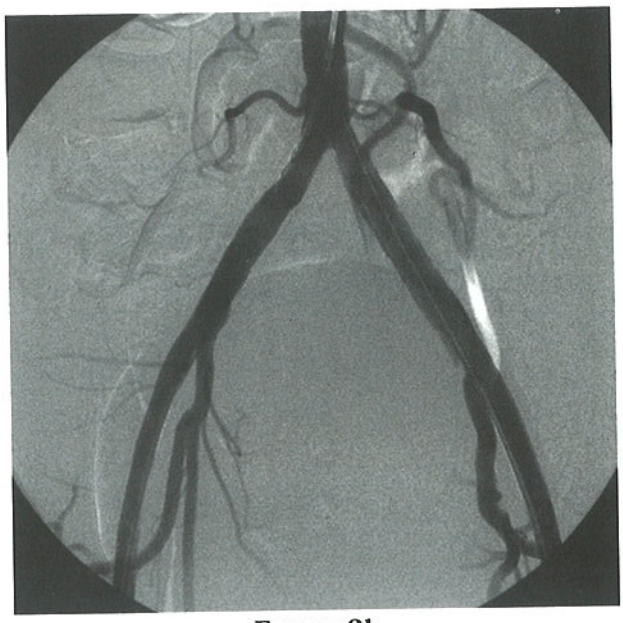

FIGURE 3b

Recanalisation of an occluded common iliac artery by use of balloon angioplasty and additional stent placement.

Endarterectomy for occlusive disease of the aorto-iliac segment

In general, endovascular treatment fails in its purpose to correct category four iliac lesions.

These include a) stenoses greater than 10 cm in length or occlusions greater than 5 cm in length, b) extensive bilateral aorto-iliac atherosclerotic disease, c) combination of iliac stenosis and abdominal aortic aneurysm or any other lesion requiring aorto-iliac surgery.

Nowadays, however, extended stenotic or occluded iliac lesions can be treated by minimally invasive remote endoarterectomy combined with endoluminal stent placement. The operative technique is similar to the semi-closed endarterectomy using an arteriotomy at the distal part of the common femoral artery. After meticulously dissecting the intimal core, a ring stripper is advanced proximally beyond the affected segment or up to the origin of the common iliac artery. Then, the ring stripper is exchanged for a Mollring Cutter^{TM} (27), which is a modification of the ring stripper, originally described by Cannon in 1955 and Vollmar in 1967. The metal shaft has a double ring construction at the distal end, replacing the single ring found on a conventional ring stripper. Both rings have sharpened cutting edges on the inner side, mimicking a pair of scissors as the lower ring shears along the upper ring when a trigger is pulled (figure 4). This remote transection device of the distal core makes it possible to endarterectomize an entirely occluded common iliac artery through a single incision at the groin. The above mentioned technique has been detailed by Ho et al. (28) for endarterectomy of the superficial femoral artery.

After the remote endarterectomy, the disobliterated iliac artery should be visualized by radiological examination. The proximal cut off point of the intima can be stented.

As part of an FDA trial the authors employ a recently developed aSpire® Covered Stent (Vascular Architects). This stent is made of nitinol and manufactured in a double spiral configuration. It is then covered by a thin sleeve of PTFE, to preclude any blood to metal contact. The spiral design is chosen for better hemodynamic compatibility whilst the native vessel and the concept of partial coverage is intended to inhibit intimal hyperplasia.

Furthermore the double helix configuration makes the stent flexible with preserving side branch access and maintaining collaterals (figure 5). No studies have been published, but the first experiences of the authors with the above mentioned technique and the aSpire® covered stent in the iliac section, are promising.

More extensive atherosclerotic disease will require more invasive (surgical) techniques.

Extensive aortic stenosis or occlusions and type I aorto-iliac atherosclerosis (limited to the infrarenal aorta and the common iliac arteries) can be treated by thrombo-endarterectomy.

This is a useful option in cases of hemodynamically significant restenosis after PTA with or without additional stent placement in young patients, or in the treatment of infected aortic grafts.

A nice helpful instrument in aorto-iliac semi-closed endarterectomy is the "plaque-cracker" (figure 6) described by Le Veen and coworkers (29). The jaws of the instrument are placed around the artery, and through the discharge of a coiled spring, a shock wave causes a

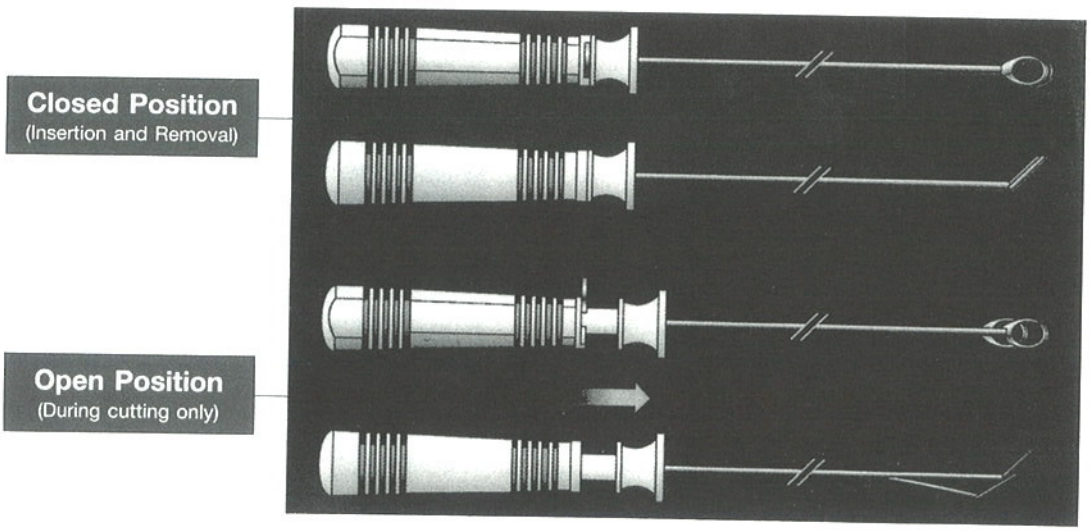

FIGURE 4
The Mollring Cutter&trade used in remote endarterectomy for both superficial femoral and common iliac arteries.

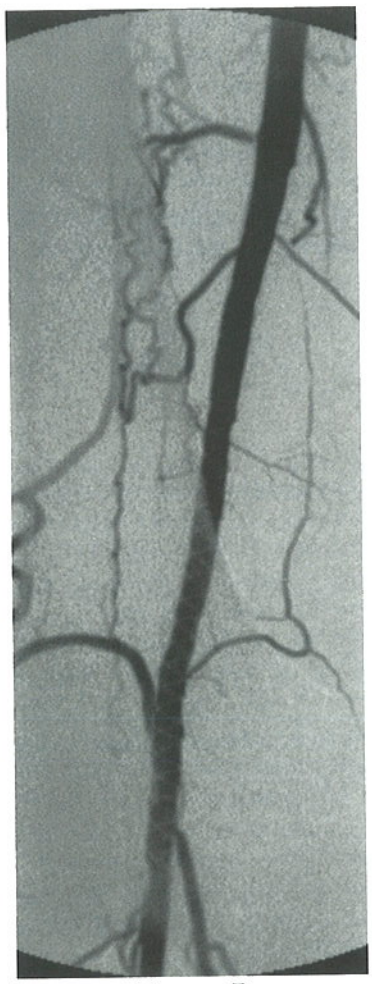

FIGURE 5
Preservation of arterial side branches after placement of the Aspire® covered stent.

sharp transection of the intimal plaque, leaving the surrounding adventitia intact. Using this plaque cracker both at the aorta and iliac arteries the dislodged atherosclerotic plaque can be extracted by a small transvers arteriotomy in the lower abdominal aorta. In most cases, the distal dissection sides need no additional tacking sutures. When the atherosclerotic lesions extend into the external iliac arteries, a surgical bifurcation bypass grafts can be placed. However, this is beyond the scope of this chapter.

Summary and future perspectives

The treatment of occlusive aorto-iliac disease is definitely not only surgical. During the last thirty years the endovascular approach has developed into a fully fledged treatment modality.

In particular, localized non aneurysmal lesions of the infrarenal abdominal aorta and category I to III stenotic lesions or short occlusions of the iliac arteries, are suitable for balloon angioplasty with or without additional stent placement. The endovascular treatment is safe, (cost)effective and minimally invasive with good long-term results. Stenotic lesions at the aortic bifurcation can safely be treated using the kissing balloon technique. In our opinion, usage of stents can be reserved for selected cases like recanalisation of occluded segments, primary failure or severe recoil after PTA and PTA induced dissection.

In the case of more extensive iliac stenosis and occlusion, the minimally invasive technique of remote endarterectomy with additional stent placement seems to be a worthwhile treatment modality. The development of new strategies in endovascular treatment is continual. In

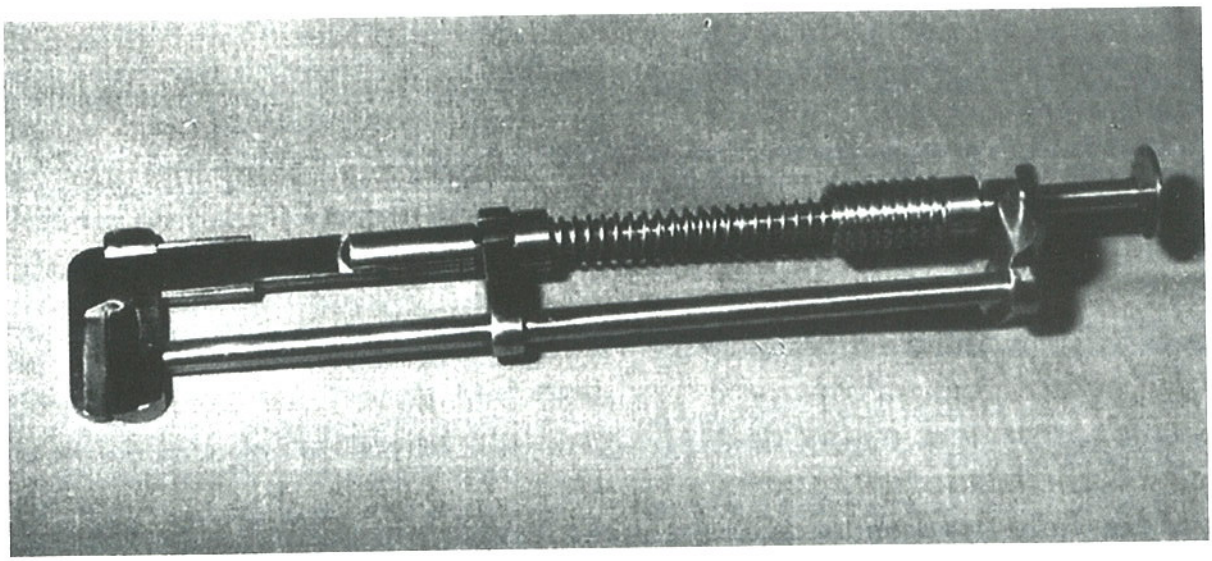

FIGURE 6
The "plaque-cracker" device developed by LeVeen.

the immediate future, stents coated with a) thrombolytic agents, b) antibiotics (e.g. the Cypherstent®, Cordis, Johnson and Johnson), c) anti-mitotic agents and/or d) radioactive forces will be tested in both research and clinical settings. It is anticipated that these coated stents will significantly decrease the present rate of in-stent restenosis.

More extensive aorto-iliac occlusive disease still requires surgical intervention such as thrombo-endarterectomy or aorto bi-femoral grafting.

But in view of the above, it is most important to note that patients suffering from occlusive aorto-iliac disease benefit most from a treatment conducted by a team of both vascular surgeons and interventional radiologists. Such teams may offer patients the most valuable and promising treatment in the wide range of options.

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Intra-arterial Thrombolytic Therapy for Lower Limb Ischemia

Jos C van den Berg, Frans L Moll

The treatment of acute peripheral occlusion remains difficult and controversial. Despite the progress in many areas of vascular reconstruction and endovascular techniques, acute peripheral arterial occlusion of the lower limb is still characterized by high rates of morbidity and mortality (1). Even with new treatment modalities 30-day amputation rates of between 20% and 40%, and mortality rates ranging between 12% and 48% have been reported (2). Even after several randomised studies (e.g. TOPAS, the Thrombolysis or Peripheral Arterial Surgery study (3), each with it's limitations caused by inconsistencies in study design (4)) a lot of questions regarding how, when and with what speed therapy should be started still remain. Published studies on mechanical thrombectomy are lacking. All this emphasizes the need for reporting standards (5).

In this chapter treatment using thrombolysis (either pharmacologic, mechanic or pharmacomechanic) and thrombosuction will be discussed. Indications and contraindications together with the advantages and disadvantages of each technique will be dealt with, emphasizing the practical application of each technique.

Clinical aspects

Acute critical ischemia of the leg is defined as a less than 3-week history of vascular resting pain, in combination with an ankle pressure below 40 mm Hg or ulceration of the foot. Acute limb ischemia can be divided into four clinical categories (6). These categories are summarized in table I. In cases where ischemia is severe (category IIb) pharmacologic thrombolytic therapy cannot be instituted because flow restauration cannot be achieved as fast as with immediate surgical revascularization, and tissue ischemia may progress to infarction. Primary amputation of the limb is the treatment of choice in patients with irreversible ischemia (category III), or in patients where revascularization of a severely ischemic limb could jeopardize the patient's life (7). Thrombolysis (especially high dose, bolus or pulse-spray technique) may be used to treat a severely ischemic leg. However, in cases like this one should handle very cautiously, because standard surgical techniques can achieve a more favourable outcome in a shorter period of time (7). Although some authors advocate the use of transcatheter thrombolytic therapy in category III patients (8), it is generally accepted that only category I and IIa patients are candidates for the percutaneous interventional procedures outlined below. The primary endpoint in reporting results of thrombolytic therapy in lower limb ischemia is amputation-free survival. Secondary endpoint is patency of the native artery or bypass thrombolyzed (7).

The two main causes of acute limb ischemia are either embolism or thrombosis. The clinical diagnosis of arterial embolism in the leg is not always possible, and may be clinically impossible in 10% to 15% of cases (2). However, it may be suggested on the basis of the following criteria (7): sudden onset of symptoms, presence of an embolic source, absence of a history of claudica-

TABLE I
Clinical categories of acute limb ischemia (6)

Category	Description	Findings		Doppler signals	
		Sensory loss	Muscle weakness	Arterial	Venous
Viable (I)	Not immediately threatened	None	None	Audible	Audible
Threatened marginally (IIa)	Salvageable if promptly treated	Minimal/none	None	Inaudible	Audible
Immediately threatened (IIb)	Salvageable with immediate vascularization	More, rest pain	Mild/moderate	Inaudible	Audible
Irreversible (III)	Major tissue loss or permanent nerve damage	Anaesthesia	Paralysis	Inaudible	Inaudible

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tion and finally the presence of normal pulses and Doppler systolic blood pressures in the unaffected limb. Emboli tend to lodge at the common femoral bifurcation, while acute thrombosis usually occurs in the superficial femoral artery (Figure 1) (1,9). A different approach is necessary for acute thrombosis and embolic occlusions. Emboli may consist of old thrombus and atherosclerotic plaque, and thus are less amenable to thrombolysis (7).

Thrombolysis

Pharmacologic thrombolysis

The treatment of acute arterial occlusions using thrombolytic therapy has several advantages over surgical thromboembolectomy. The underlying stenosis can be localized and depicted, facilitating better planning of additional surgical or endovascular intervention (10). Such morphological abnormalities are revealed in up to 86% of cases (11). The nature of the additional intervention is dependant on the characteristics of the unmasked lesions (neointimal or atherosclerotic, diffuse or focal). Furthermore thrombolysis is less traumatic to the vessel wall than thrombectomy using Fogarty balloons (the original construction of which precludes steering and advancement over a guide wire, thus causing more subintimal dissection (12)), and thrombus in small vessels (lower leg) can be treated better using thrombolysis. If surgical embolectomy is performed without angiographic or fluoroscopic control, incomplete clot removal can occur in up to 30% of cases (13). Complications of balloon thromboembolectomy can be diminished by the standard use of fluoroscopy during the procedure (14). Besides these advantages, there are drawbacks to thrombolysis, including the below mentioned hemorrhagic complications (including stroke), and renal impairment due to repeated angiography. Furthermore there is a significant expense, not only due to the cost of the thrombolytic agent, but also due to the need for serial angiography and intensive care patient surveillance (15).

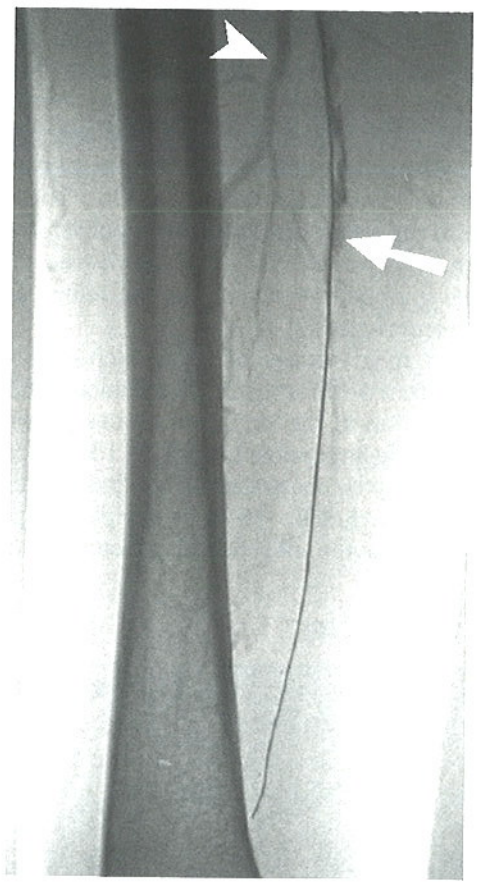

FIGURE 1
Guide-wire can be seen passing through thrombus (outlined by contrast, arrow); note good filling of deep femoral artery (arrow-head; this virtually excludes embolic origin of occlusion)

The final common pathway in the formation of clot is the cleavage of fibrinogen into fibrin by thrombin. Fibrin strands enmesh aggregated platelets and erythrocytes, thus forming thrombus. Breakdown of the thrombus occurs by the generation of plasmin, that is formed from plasminogen (16). All types of pharmacologic treatment of acute peripheral occlusion (streptokinase, urokinase, and recombinant tissue plasminogen activator (rTPA)) have in common that they in one way or another influence plasminogen levels (either circulating or tissue-bound). The plasmin formed by this interaction induces degradation of fibrinogen, factor V, and factor VIII, and can also influence platelet function (17). Long-term use of these drugs can cause bleeding complications, not only at the site of arterial or intramuscular punctures, but also at remote sites (e.g. digestive tract, brain). The ideal thrombolytic has not yet been found, but it should have the following properties: it should be clot-specific, without influence on circulating coagulants; it should induce complete lysis of fresh and old thrombus without embolic complications; it should be short-acting; and it should leave endothelium intact. It should prevent rethrombosis and, finally, it should lack systemic effects. For as long as this drug does not exist, however local thrombolysis is preferred over systemic administration of the thrombolytic agent, on the basis of several (theoretical) considerations: the drug only acts within the thrombus and is protected from antibodies; infusion time is short; the occurrence of a systemic lytic state is prevented; and, finally, costs are lower (18). Several infusion methods exist. Continuous infusion uses a constant infusion pump at a steady flow. Stepwise infusion consists of the placement of the catheter tip within the proximal part of the thrombus,

and advancing the catheter as the thrombus dissolves. Graded infusion refers to an infusion protocol with diminution of infusion rates, the highest doses given in the first hours (19). A forced periodic infusion (e.g. pulse-spray) consists of a technique where the thrombolytic agent is forcefully injected into the thrombus, fragmenting the thrombus and thus increasing the surface available for thrombolysis.

The indications for arterial pharmacologic thrombolytic therapy are as follows: arterial thrombus less than 3 months old, acute thrombosis after or during endovascular procedures, peripheral emboli, pre-treatment of atherosclerotic plaques or short occlusions, peripheral bypass graft thrombosis more than 4 weeks after surgery, or thrombosis of dialysis fistulae. Intraoperative lytic therapy (20) is beyond the scope of this chapter. As already mentioned before, proper selection of patients is critical: in close cooperation between interventional radiologist and the (vascular) surgeon, an evaluation is carried out as to whether the patient can tolerate the ischemia any further (cf. coronary ischemia).

The following are considered as contraindications: active lesions in the central nervous system, severe uncontrolled hypertension (>180 mm Hg systolic,or >110 mm Hg diastolic), active bleeding, recent gastrointestinal bleeding (<10 days),hemorrhagic diabetic retinopathy, and severe ischemia with loss of sensory and motor function. Relative contraindications are: pregnancy, recent surgery or biopsy (<10 days), hip surgery within the previous 21 days, advanced uraemia, hepatic failure, cardiac thrombus, malignancy, history of cardiopulmonary resuscitation (<10 days), hematuria, or complete stroke within the previous 3 months (18).

When pharmacologic thrombolysis is the therapy of choice several treatment options are available.

Streptokinase

Streptokinase is produced by cultures of Lancefield group C, b-hemolytic streptococci. Streptokinase is an indirect activator of plasminogen. The advantage of streptokinase is its relatively low cost. The major disadvantage is the possibility of an allergic reaction (streptokinase is a foreign and therefore antigenic protein, unlike urokinase and rTPA (17)). Because of its allergenic properties, repeat treatment using streptokinase within 6 months of an earlier administration is considered to be contraindicated. Finally streptokinase has significant fibrinolytic effects.

Urokinase

Urokinase is extracted from human urine or from long-term cultures of human neonatal kidney cells. Urokinase is a direct activator of plasminogen, and causes fewer coagulation abnormalities than streptokinase (21). Low- or high-dose slow infusion (60,000 U/h vs 250,000 U/h), or high-dose pulsed spray infusion of urokinase have been reported in the literature. The latter technique requires extra investment for special catheters and infusion pumps. The reduction of total procedure time using the pulsed spray technique claimed by some authors (4,4,22-25) has not been reproduced by others (26).

The results of treatment do not differ much. The advantage of urokinase is its slightly shorter half-life, the lower incidence of systemic complications (especially using a low-dose protocol), and a lower incidence of allergic reactions. Its disadvantage is its relative high cost.

Recent developments have been recombinant human urokinase and recombinant glycosylated pro-urokinase. These two agents have shown to be effective, without inducing fibrinogen depletion (see below) (27).

Recombinant tissue plasminogen activator (rTPA)

rTPA has relative fibrin selectivity and causes less fibrinogenolysis than streptokinase (28). The use of rTPA in the treatment of acute peripheral arterial occlusions is not yet widespread in Europe, partly due to the high cost of the product (although in the USA due to FDA regulatory problems with urokinase, rTPA is being used more frequently). The optimal dosage and administration technique of rTPA have not been established yet in formal clinical studies (16). Clinical results are comparable to those of urokinase treatment (29). In general thrombolysis is achieved faster, though at the cost of a higher incidence of complications (30) (see below).

Table II summarizes the characteristics of the above mentioned drugs. An overview of dosage schemes used in the past can be found in the publication of the "Working Party On Thrombolysis In The Management Of Limb Ischemia" (7).

All the above-mentioned treatments can be combined with complete heparinization of the patient (1000 IU/h i. v.), in order to prevent pericatheter thrombus (or at least reduce the incidence of pericatheter thrombus to 3%) (7,19). One commonly used technique consists of a contralateral, retrograde arterial puncture using a 4- to 5-F multihole catheter, positioning the catheter after crossing the bifurcation above the occluded segment. After diagnostic angiography an attempt is made to pass the thrombus with the guide-wire (the guide-wire traversal test; Figure 1). A positive guide-wire test predicts a higher success rate (7,18,19,31). As the next step, the catheter is positioned several centimeters inside the thrombus and infusion of the thrombolytic is started. The inability to embed a catheter in the proximal thrombus is a predictive factor for the failure of throm-

TABLE II
Properties of thrombolytic drugs

	Streptokinase	Urokinase	rTPA
Antigenic	Yes	No	No
Plasma half-life	18 min	11 min	5 min
Duration of treatment	>48h	48h	8h
Relative cost	1	10	20

bolysis (7,31). Furthermore the length of the occlusion appears to predict whether a patient will be treated best with catheter-based thrombolytic therapy or surgery, with longer lesions responding better to an initial thrombolytic therapy (32). Regular controls are mandatory and make the treatment rather time-consuming. After restoration of blood flow within the occluded arterial segment or bypass, the underlying causes must be treated by either angioplasty or surgery. When there is any doubt about the nature of any residual stenosis (residual thrombus or atheroselerotic plaque), thrombolysis must be continued.

Complications can be either thromboembolic or hemorrhagic. The latter may be local (at the puncture site) or distant (cerebral, gastrointestinal, or retroperitoneal). Hemorrhagic complications of urokinase and rTPA are significantly correlated with fibrinogen depletion (33). Severe systemic or intracranial bleeding is the most significant clinical risk associated with any thrombolytic therapy. These complications may be due to lysis of a preexisting hemostatic plug, an anticoagulated or fibrinolytic state or loss of integrity of a vessel via an already established puncture.

The introduction of local infusion of thrombolytic has reduced the incidence of complications dramatically but has not eliminated them completely. Severe hemorrhagic complications are reported to occur in up to 12% of patients treated with low-dose urokinase, 32% of those treated with streptokinase, and 43% who receive high-dose urokinase treatment (3,19,33-35). rTPA has been reported to have a higher incidence of bleeding complications as compared to urokinase (46% rTPA versus 9% urokinase) (21). The overall risk of hemorrhagic stroke is estimated to be 1%, and is a fourfold greater with rTPA than with urokinase (36,37). When a distant hemorrhagic complication occurs the infusion of the thrombolytic agent has to be stopped immediately (7). The effect of the heparin can be stopped using protamine. Coagulation factors (e.g. fresh frozen plasma, cryoprecipitate) can be replenished and blood can be given. In cases of persistent bleeding, amino-capronic acid can be administered, but its use remains controversial (7).

Bleeding from a puncture site can be controlled with local compression, placement of a larger sheath or catheter, and finally by a surgical stitch.

Thrombolytic therapy can also induce emboli, locally in the treated limb or distant from the treated site. The latter are usually caused by lysis of intracardiac thrombi. Local embolic complications occur in 2-9% of cases, and are caused by fragmentation of partially lysed thrombus (Figure 2). The symptoms of ischemia (acute pain, paresthesia) can even worsen.
When treated adequately by repositioning the catheter in the embolized segment, clinical sequelae are absent.

Finally a compartment- or "crush" syndrome can occur due to reperfusion and hyperemia of the treated limb, with incidence rates ranging from 0 to 4.1% (38). Reperfusion syndrome refers to the damage done by restoration of blood flow to the damage done by restoration of blood flow to ischemic tissue and has to be viewed separately from the original ischemic insult (39). The crush syndrome is characterised by shock, myoglobinuria, hyperkalemia, and cardiac conduction abnormalities (40). Gradual, low-pressure reperfusion is believed to be associated less frequently with reperfusion syndrome than sudden high-pressure reperfusion, because gradual reperfusion may avert the sudden release of anaerobic metabolites into the systemic circulation (15).

A Cochrane review on surgery versus thrombolysis (41), revealed that there is no available evidence to advocate a universal treatment with either surgery or thrombolysis. The efficacy and safety of pharmacologic thrombolytic therapy for the lower extremity have been addressed in several single center studies and three large prospective randomised trials. The findings of these studies are conflicting, and each study has it's limitations (15). In the Rochester trial, that studied a group of 114 patients with a new onset lower extremity ischemia of less than 1 week duration, the limb salvage rate was identical in both catheter directed thrombolysis and surgery groups. The patients treated with urokinase had improved survival rate, due to fewer perioperative cardiopulmonary complications (42). The STILE (Surgery versus Thrombolysis for Ischemia of the Lower Extremity) trial initially demonstrated a lower amputation rate for thrombolytic therapy (either urokinase or rTPA) as compared with surgery in patients with symptoms persisting less than 14 days. However, in patients with prolonged symptoms surgery appeared to be more successful (43). Reanalysis of the data, focusing on native arterial occlusions, demonstrated initial surgery to be superior to thrombolysis, irrespective of the length of the ischemic period (44). In occluded bypass grafts the duration of the symptoms (less than 2 weeks) is an important factor considering thrombolytic therapy (44). Finally the TOPAS (Thrombolysis or Peripheral

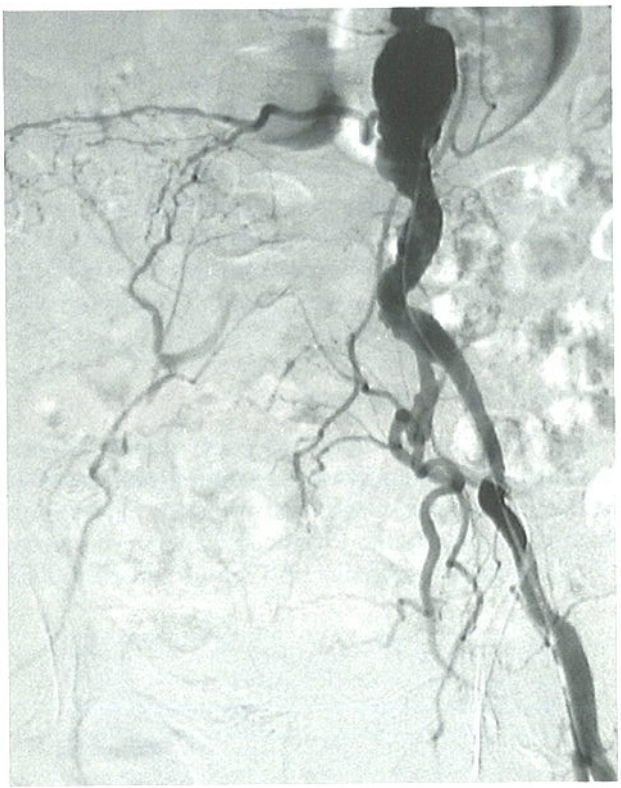

FIGURE 2a

Acute occlusion of right common and external artery (angiography performed from contralateral groin)

Arterial Surgery) trial demonstrated that in a patients with symptoms persisting less than 14 days, the amputation-free survival at 6 months was equal for surgery and thrombolytic therapy. The authors concluded that with equivalent outcomes, the least invasive technique would be the preferred intervention (i.e. thrombolysis) (4).

Thrombolysis may be associated with a higher risk of ongoing limb ischemia, and a higher overall risk of hemorrhagic complications, including stroke (41).

From a cost-effectiveness point of view however, initial surgery provides the most efficient and economic utilization of resources for the acute ischemic leg (45). Thrombolysis can be as costly as or more costly than surgery for the treatment of native arterial occlusions of the lower extremities (15). The high cost of thrombolysis is related to the expense of the lytic agent, but also the need for additional interventions (including costs of amputation in cases that failed to respond to thrombolytic therapy) (45).

Success rates as described in the literature vary from 22% (streptokinase) to 90% (urokinase), and are higher in patients with occluded bypass grafts than in those with occluded native arteries (3,4,46-49). Two trials indicate that thrombolysis is the preferred option to restore patency of grafts occluded less than 2 weeks (13,50,51), and can provide a beneficial reduction in the surgical procedure for a majority of patients. Thrombolysis is able to reduce the magnitude of required subsequent surgery, by facilitating the angioplasty of underlying arterial lesions (52). On the other hand thrombolysis has worse long-term limb salvage rates than surgery, especially for patients with a native femoropopliteal occlusion, diabetes or critical limb ischemia (44).

A systematic review of intra-arterial thrombolytic therapy for lower-limb ischemia demonstrated that there still is insufficient evidence for the widespread use of thrombolysis, except in graft occlusions and short-duration ischemia (28).

Laboratory testing during the procedure include prothrombin time (PT), partial thromboplastin time (PTT), fibrinogen, and fibrin split products every 4-6 h. Fibrinogen levels are estimated in order to monitor the possible development of a systemic fibrinolytic state. PTT levels are kept at 1.5-2 times normal (indicating proper dosage of the heparin) (17).

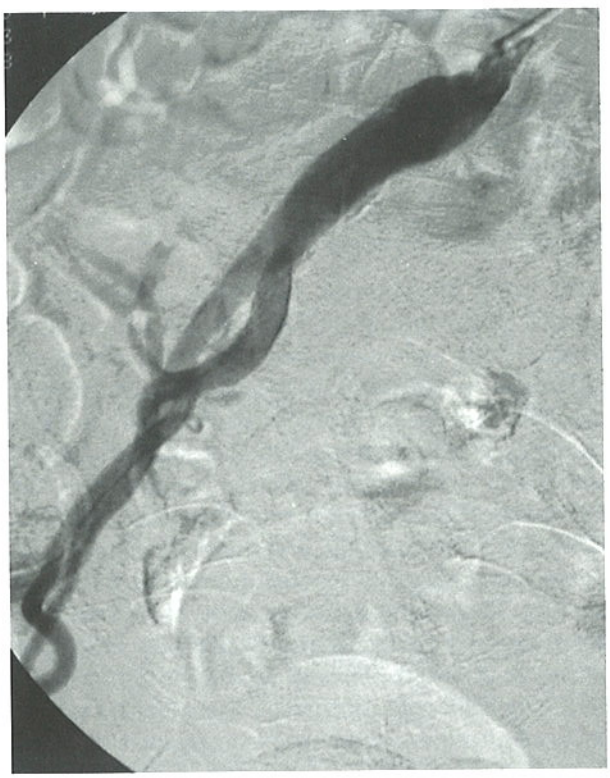

FIGURE 2b

After 24 hours of thrombolytic therapy using urokinase (90.000 U/hr) complete restoration of patency of iliac artery.

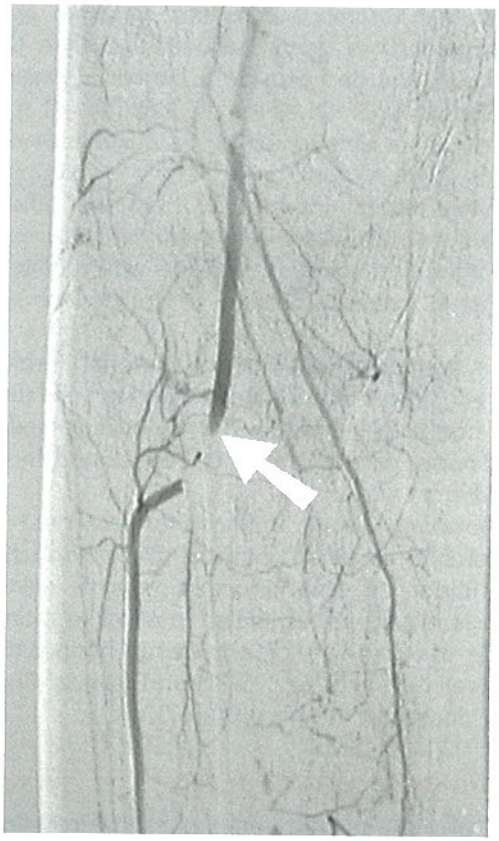

FIGURE 2c

Control angiography of the lower leg in the same patient demonstrates distal embolization of lysed fragments into peroneal trunk (arrow)

Mechanical thrombolysis

To avoid the systemic and local complications of pharmacologic thrombolysis, various thrombectomy catheters have been developed. The main advantage of mechanical thrombolysis is the decrease in procedure time that can be achieved, and the lack of (distant) hemorrhagic complicatons. Other advantages are that mechanical thrombolysis typically requires one single session (as compared to the multiple examinations with farmacologic thrombolysis, and does not require intensive care monitoring and repetative (expensive) laboratory tests (53). The relative disadvantage of the currently available systems is the fact that only relatively fresh thrombus (up to 2 weeks old) can be thrombolyzed (54,55), and it is unlikely that mechanical thrombolysis will completely eliminate the need for pharmacologic thrombolysis or open surgery (56). Mechanical techniques are still considered experimental (7). The systems can be classified into five categories (56-59). Systems using recirculation (pulverisation of thrombus by a hydrodynamic vortex created by a high-speed impeller) form the first category (e.g. Amplatz and Trac-Wright catheter). The second category is hydrodynamic thrombectomy (using the Venturi effect). Aspiration thrombectomy or suction thromboembolectomy is the third category. Non-recirculation thrombectomy, the fourth category uses catheters with a low-speed rotational mechanism with concomitant suction (rotating propeller or cutting blades, e.g. Terotola thrombolytic device and Castaneda brush catheter). The last category is the so-called special energy-assisted thrombectomy that uses ultrasound, radiofrequency or lasers to fragment the thrombus.

Hydrodynamic thrombolysis

Hydrodynamic thrombolysis uses special catheters and/or special equipment. All commercially available systems (Hydrolyser, Oasis, and Angiojet; Figure 3) use a high-velocity saline flow that causes negative pressure at the multilumen catheter tip (Venturi effect) (60-62),

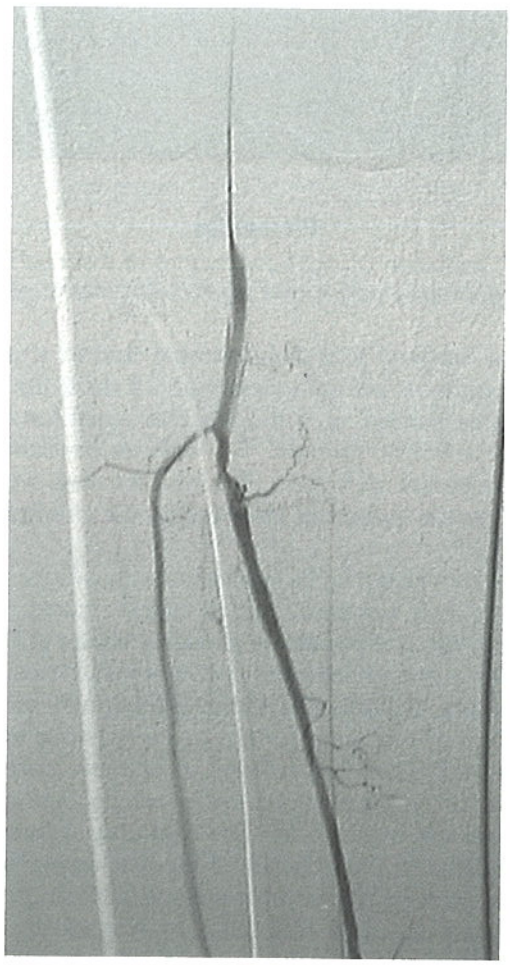

FIGURE 2d

After advancement of the catheter into the popliteal artery and continuation of lytic therapy complete restoration of patency is achieved

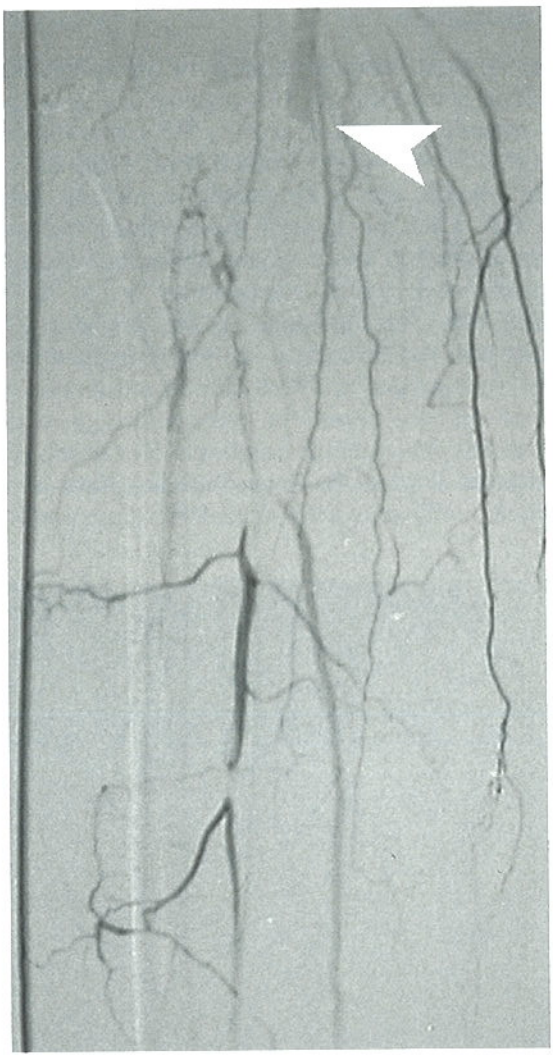

FIGURE 3a
Occlusion of popliteal artery (arrowhead) due to thrombus in a patient after removal of intra-aortic balloon-pump from the right groin

and in this way thrombus is aspirated in the outlet lumen of the catheter. The advantage of the Angiojet system is the small caliber of the catheter (3.5 F). The disadvantage is the high cost of the ancillary equipment necessary for the aspiration. Furthermore, using this system, a fair amount of blood will be aspirated during the procedure, limiting the total aspiration time to 15 min. The high-velocity saline flow for the Hydrolyser and Oasis catheters is obtained with the aid of a standard mechanical contrast injector. The disadvantage is the relatively large caliber (6 F), and with both systems blood will be aspirated as well (20% of the aspirate consists of blood). Hydronamic thrombolysis may cause hemolysis, and possible renal failure secondary to the release of free hemoglobin. Another possible adverse effect may include fluid overload from the saline jets (59).

The primary success rate of this technique is reported to be 50%. Additional treatment with pharmacologic thrombolysis and/or angioplasty remains still necessary, but in this way a success rate of 100% can be achieved (60-62). In an experimental setting endothelial damage of the vessel treated was seen in all cases (58).

Macerating mechanical thrombolysis

Macerating thrombolysis devices (e.g., Amplatz clot macerator (55), and Rotarex (57)) are reported to give equal results, with clinical success rates ranging from 77% to 100% (54). Each device has its own limitations, including restriction to fresh thrombi only, incomplete clot removal, vessel wall damage or complex design. In vitro evaluation of the Amplatz thrombectomy device showed similar efficacy of the 6F and 8F system in vessels up to 7 mm in diameter (63).Additional pharmacologic thrombolysis is, however, necessary in nearly all cases (54).

Mechanical thrombolysis (using hydrodynamic and macerating mechanical systems) can cause peripheral

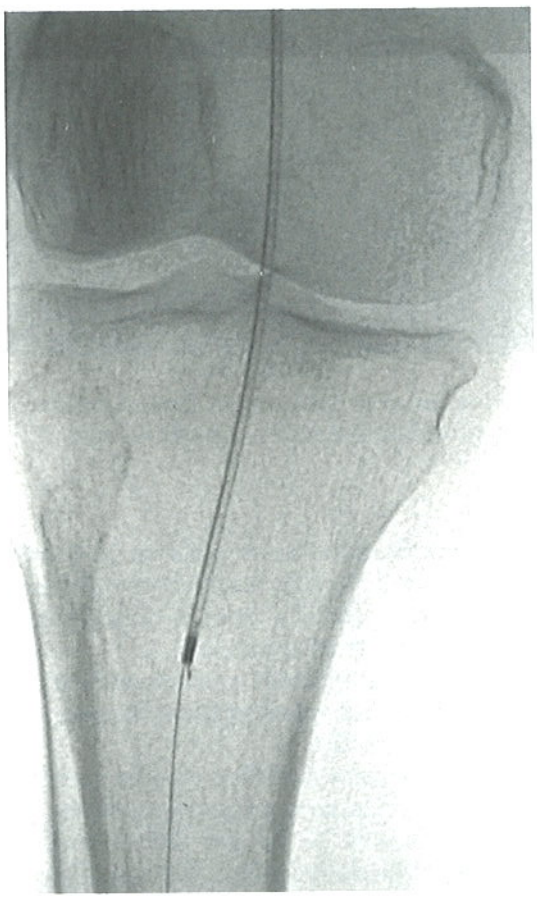

FIGURE 3b
Hydrodynamic thrombectomy catheter in position

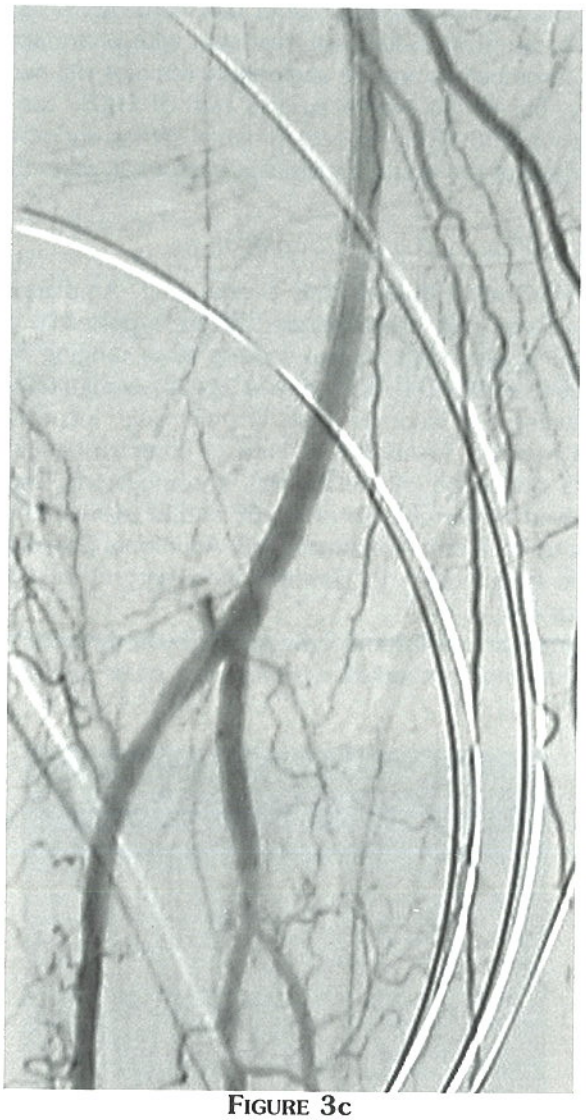

FIGURE 3c
Final angiographic result demonstrating complete patency of popliteal artery

emboli, a complication that is reported to occur in 4-25% of cases (54, 55, 61). Another complication seen relatively frequently (28% of cases in a study population of 18 patients) is arterial spasm (64).

Long-term patency rates vary depending on the system used, but in the reported 6 months patency rates range from 43-78% (56).

The ideal treatment algorithm may be presented by the initial use of a mechanic thrombolytic device, with or without pre-treatment of the clot with a thrombolytic agent, followed by a short duration pharmacologic thrombolysis to clean up residual thrombus. Finally subsequent correction of the often present culprit lesion by either endovascular or open surgical repair should follow (56).

Thrombosuction

Percutaneous thrombosuction or aspiration thromboembolectomy (12, 65, 66) requires the least investment regarding materials: a 8- to 9-F aspiration catheter and a 50-ml syringe suffice. Preferably an introduction sheath with a removable hemostatic valve is used (63). Like mechanical thrombolytic therapy, it can be applied in cases where fibrinolytic therapy is contraindicated, which happens in up to 20% of patients (59). After passage of the single-end- hole catheter into the thrombus, suction is applied using a 50 ml syringe and the catheter is withdrawn. The obtained aspirate should be passed through a gauze swab. In this way sizeable (remnants of) thrombus may be removed (Figure 4). In-vitro studies have demonstrated it's efficacy, with acceptably low peripheral

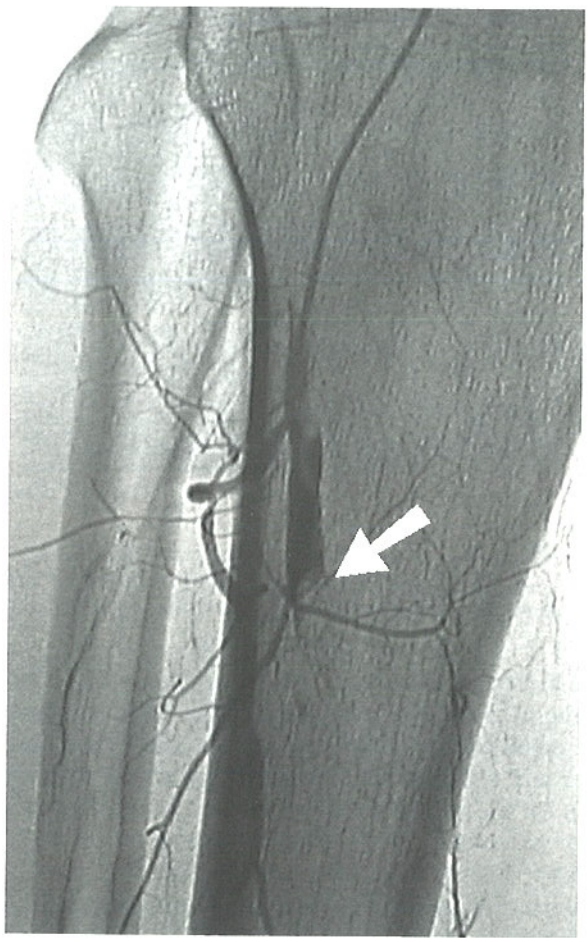

FIGURE 4a
Acute occlusion of peroneal trunk (arrow) due to thrombo-embolus after balloon angioplasty of longer standing occlusion of distal superficial femoral artery

embolism rates (67). After several passes of the catheter (partial) restoration of blood flow can be achieved in 3-96% of cases (68). Results are better with embolic occlusion than with in situ thrombosis (69). Wall-adherent thrombi cannot generally be removed completely. Adjunctive procedures (thrombolysis, stent placement) can increase the success rate to 86-93% (54,65). As compared to the use of thrombolysis alone, percutaneous aspiration thromboembolectomy can significantly reduce the time required for clot dissolution (66, 70), and reduction in the number of hemorrhagic complications and cost 12,70. Long-term clinical success rate is favourable (81.7% at one year) (68). Disadvantage of percutaneous aspiration thromboembolectomy is that its use is limited to the treatment of acute thromboembolism.

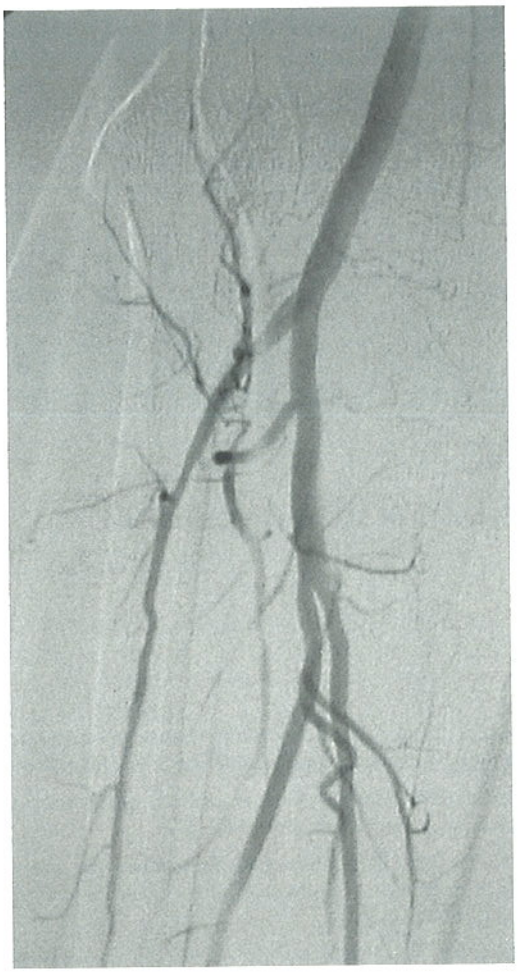

FIGURE 4b
Control angiography demonstrating patency of the peroneal trunk

Conclusion

In conclusion, many different treatment options exist for the patient suffering from acute limb ischemia. The ideal treatment modality would have to be minimally invasive and result in a rapid restoration of bloodflow, criteria not met by either of the above mentioned techniques. None of the therapies discussed is superior to another, and different therapies should not be regarded as competitive but as complementary and synergistic (Figure 5). Knowledge of the capabilities of a particular technique and close cooperation of the vascular surgeon with the interventional radiologist is of utmost importance in order to offer the patient the best available therapy.

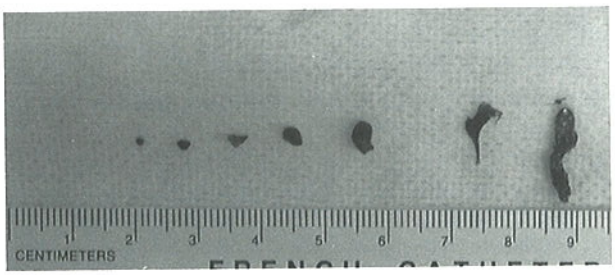

FIGURE 4c
Fragments aspirated using thrombosuction, partly organized, partly fresh thrombus

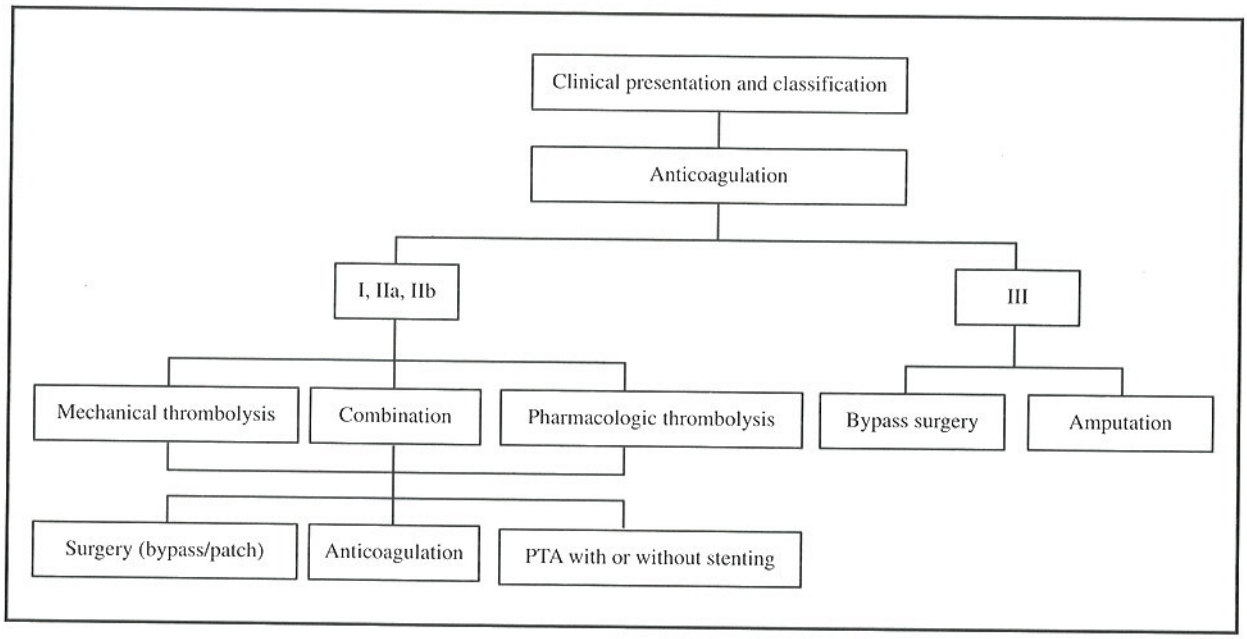

FIGURE 5
Flow chart management of acute limb ischemia (adapted from reference (1) and (10))

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Percutaneous Transluminal Angioplasty for Critical Limb Ischemia

Edward B. Diethrich, Julio Rodriguez-Lopez, Venkatesh Ramaiah

Critical limb ischemia may be the product of acute or chronic disturbances of blood flow in the lower extremities. Chronic arterial occlusive disease causes arterial narrowing or obstruction that reduces blood flow to the lower limb during exercise or at rest, yielding a variety of symptoms, including intermittent claudication, and in severe cases, critical ischemia that imperils part or all of the lower extremity (1). The superficial femoral and popliteal arteries are most often affected by the atherosclerotic process, and the distal aorta and its bifurcation into the two iliac arteries are the next most frequent sites of involvement. As many as 5% of men and 2.5% of women 60 years of age or older have symptoms of intermittent claudication, (2,3) and noninvasive diagnostics reveal a considerably higher prevalence of the disorder (4). Approximately 15% to 20% of patients with lower extremity arterial disease will progress from intermittent claudication to critical limb ischemia over the course of their disease (3,5).

In general, the primary indications for an interventional procedure in patients with lower extremity occlusive arterial disease include:

1. incapacitating claudication interfering with work or lifestyle;
2. limb salvage in patients with limb-threatening ischemia as manifested by pain at rest, non-healing ulcers, and/or infection or gangrene; and much less frequently;
3. vasculogenic impotence (6).

Acute limb ischemia is defined as any sudden decrease or worsening in limb perfusion causing a potential threat to extremity viability.

There are three clinical categories of acute limb ischemia:

1. viable-not immediately threatened;
2. threatened-salvageable with immediate revascularization;
3. irreversible-major tissue loss inevitable (7).

The degree of ischemia may well dictate the potential for success of treatment. For example, a patient with a chronic popliteal arterial occlusion, trifurcation disease, and an open ulcer of the great toe is in a distinctly different category than one who presents with a sudden occlusion of an above-the-knee femoral-popliteal bypass graft and a cool, pulseless foot that shows signs of neurological compromise. While endovascular treatments are available for each of these patients, the modalities that will provide successful outcomes in each of these cases are likely to be quite different.

Indeed, there are a variety of therapies – surgical and endovascular – used to treat patients with lower extremity arterial disease, and most of these treatments have some application in critical ischemia.

These procedures include bypass surgery, thrombectomy, thrombolysis, rheolysis, standard and subintimal angioplasty, laser angioplasty, stenting, and endoluminal grafting. In some cases, several techniques may be used to optimize outcome (Figure 1). Our focus in this chapter will be on angioplasty techniques and clinical results in patients with occlusive lesions creating critical limb ischemia.

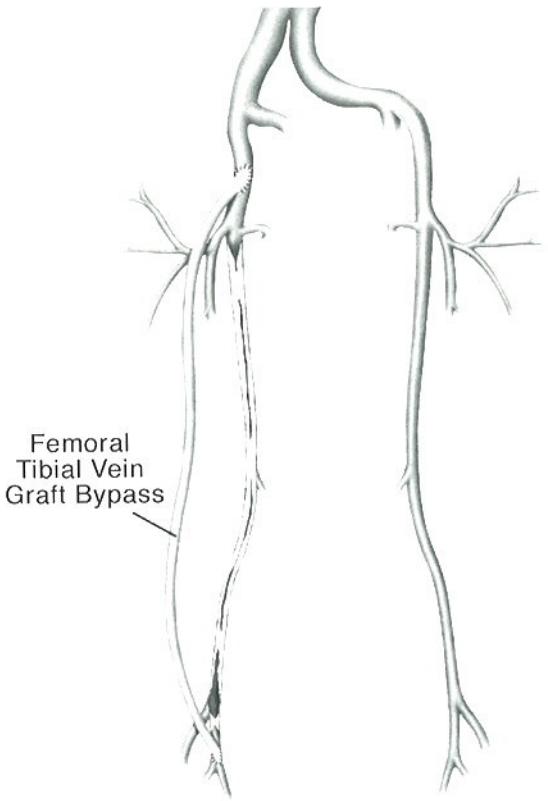

FIGURE 1a

From Critical Lower Limb Ischemia Edited by R Bartolucci, L Battaglia, V D'Andrea, E De Antoni ©2002

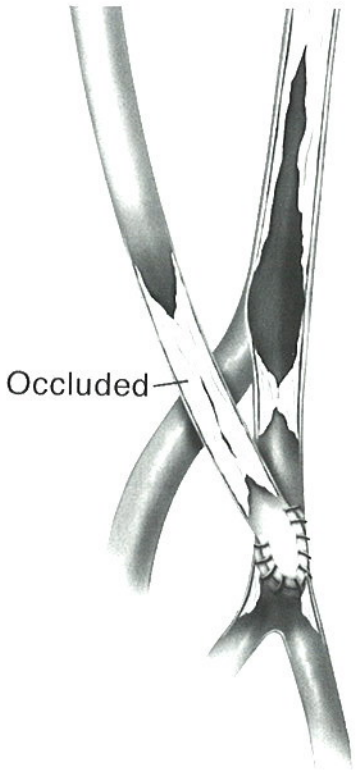

FIGURE 1b

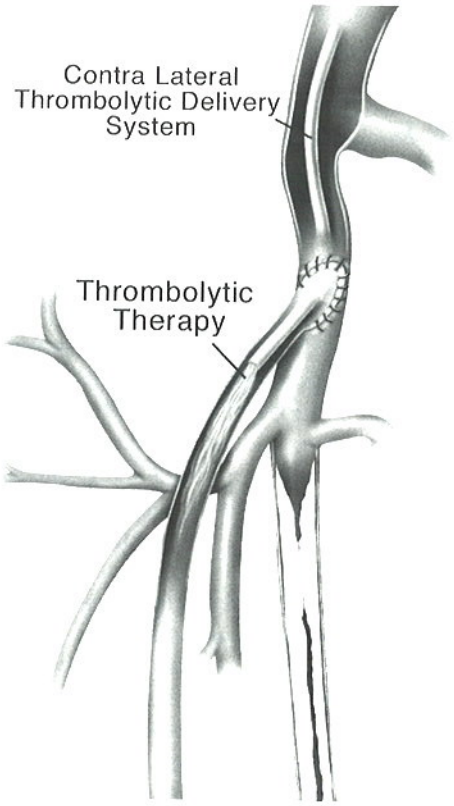

FIGURE 1c

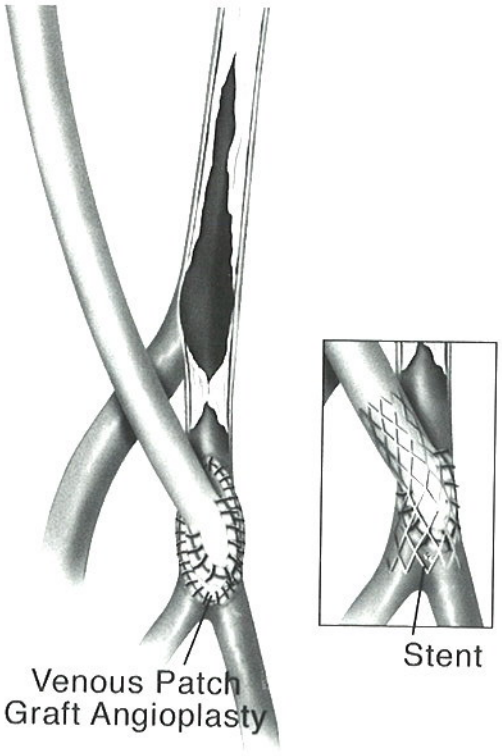

FIGURE 1d

Acute occlusion of a femoral-popliteal or tibial bypass is a common cause for acute limb ischemia and requires immediate intervention. As illustrated, a) femoral-tibial vein bypass, b) occlusion of bypass graft secondary to progressive distal disease in the tibial-peroneal trunk, c) successful opening of the bypass graft using thrombolytic therapy, and d) procedure complete with venous patch-graft angioplasty of the distal anastomosis – deployment of an endoluminal stent has also been successful in these secondary procedures.

Angioplasty: An Overview

Standard balloon angioplasty techniques have been in use for several decades, and in 1984, the Council for Scientific Affairs of the American Medical Association stated "angioplasty is an acceptable procedure in selected patients as an alternative to bypass grafting." (8) In addition, the 1983-1984 Health and Public Policy Committee of the American College of Physicians concluded "the morbidity in the periphery is less than for surgery." (9) Indeed, balloon angioplasty has been called a "modern-day workhorse" for percutaneous interventions in lower extremities, particularly in the iliac arteries. The procedure is generally straightforward to perform, and is considered cost-effective and safe (10).

The success of balloon angioplasty in the treatment of serious lower extremity vascular disease has been shown to depend on a variety of factors (6). Factors that adversely affect long-term patency include diabetes mellitus, diffuse atherosclerosis, limb-threatening ischemia, long or eccentric lesions, and poor initial post-angioplasty appearance. It has been suggested that only about one third of patients who require a revascularization procedure are candidates for angioplasty and that isolated case-series may overestimate the success of the procedure in limb salvage (6) Intervention is most successful in patients with stenotic rather than occlusive disease, good distal run-off, and a proximal lesion. In the iliac system, stenoses are common, while in the femoropopliteal system, occlusions predominate. When occlusive lesions are greater than 10 cm, open surgical intervention may be indicated. In patients with advanced disease and critical limb ischemia, standard angioplasty may be used in conjunction with vascular reconstruction or other techniques (6).

Whether balloon angioplasty is performed alone or as part of a "combination" therapy, patient assessment should include a history and physical exam and a detailed vascular examination. Ankle/brachial index should be measured prior to arteriography, and measurement of segmental pressures or pulse volume recordings may be helpful. Duplex scanning of the affected extremity may point to the offending lesion. A complete diagnostic arteriography has been standard practice before any vascular intervention; however, more recently, magnetic resonance angiography (MRA) has been substituted and may well become the gold standard of the future.

Patients undergoing interventional procedures should have continuous cardiac monitoring and intravenous access for the administration of fluids and medications. When conscious sedation is used, pulse oximetry is required, and intra-arterial pressure measurements are very helpful. Following the procedure, arteriography is used to document the anatomic result and identify any complications. The puncture site should be monitored following the procedure, and urinary output, cardiac symptoms, pain, and other indicators of systemic complications should be evaluated.

Subintimal Angioplasty

Subintimal angioplasty, which creates an arterial dissection in the subintimal plane of the vessel via guidewire or catheter insertion, was discovered accidentally in the late 1980s (11) and has since been used successfully to treat lower extremity occlusions, including those associated with critical limb ischemia (11-16). The technique may be particularly valuable for treating lesions in the superficial femoral artery (SFA), and both open (13) and retrograde popliteal approaches (16) have been described.

The procedure involves the opening of a subintimal channel with percutaneous insertion of needle and guidewire (14) or an incision and arteriotomy (15). After access to the channel has been created, the subintimal plane is opened distally with a guidewire, and the neolumen is expanded with sequential balloon dilations. Lesions treated with subintimal angioplasty assume a round, tubular configuration, and plaque is generally concentrated on the side of the vessel opposite the subintimal channel. In theory, the arterial wall is smoother and potentially less thrombogenic than that seen after standard angioplasty, which fractures plaque and creates an uneven surface that may stimulate hyperplasia and aggregation of cellular material. Nevertheless, the success of subintimal angioplasty has been somewhat limited in difficult-to-treat femoropopliteal lesions, with patency rates of 50-60% at 18-36 months (17,18).

Laser Angioplasty

Excimer laser angioplasty was introduced to address problems with restenosis and the need for recanalization following standard angioplasty, (19) and the Food and Drug Administration (FDA) approved clinical use of the device in 1992 for recanalization in coronary and peripheral arteries. Laser angioplasty is achieved by percutaneous insertion of a specialized catheter into the artery, where laser energy is emitted in short pulses of photons to vaporize plaque. In most cases, laser angioplasty is used in conjunction with standard balloon angioplasty. There are three types of laser energy sources used in angioplasty procedures: thermal, photothermal, and photoablative (19).

Thermal and photothermal energy are "hot" sources that have the potential to damage vessel walls-these types of laser energy are no longer used for angioplasty procedures. The photoablative excimer laser is a "cool" source that reduces carbonization and thermal damage to blood vessels and is still used for some angioplasty procedures.

The safety and efficacy of excimer laser-assisted angioplasty for recanalization of superficial femoral artery has recently been analyzed in 318 consecutive patients (207 men; mean age 64.2 +/- 10.7 years, range 33-91) with 411 SFAs (20). Chronic occlusions averaged 19.4 +/- 6.0 cm in length, and >75% of patients had severe claudication. Critical lower limb ischemia with rest pain or minor tissue loss was present in 6 and 15 patients, respectively. The mean ankle brachial index (ABI) before and after exercise was 0.62 +/- 0.15 and 0.40 +/- 0.18, respectively. The technical success rate was 90.5% (372/411), and complications

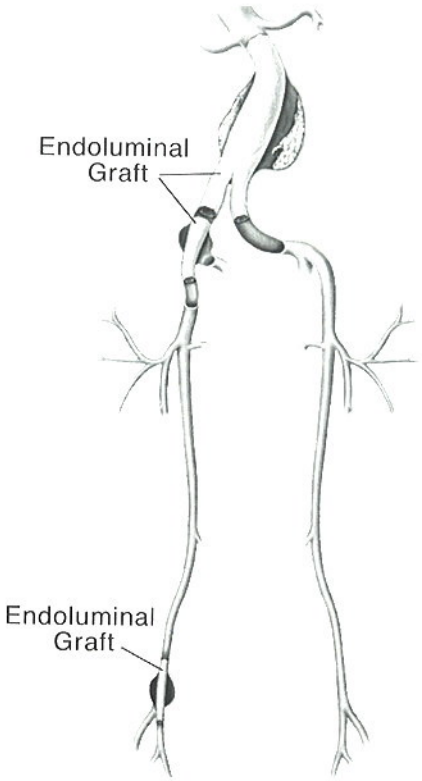

FIGURE 2

Aneurysmal disease may be a factor in acute limb ischemia in situations in which the aneurysm is a source of a distal occlusive embolus or a sudden thrombosis that limits distal perfusion.

included acute reocclusion (1.0%), perforation (2.2%), and distal thrombosis/embolization (3.9%). Following the procedure, 219 (68.8%) patients were asymptomatic, but primary patency at one year was only 33.6%. In the majority of patients, reocclusion was successfully treated on an outpatient basis. The one-year assisted primary and secondary patency rates were 65.1% and 75.9%, respectively. The authors concluded that long SFA occlusions can be recanalized safely and effectively by excimer laser angioplasty, but maintaining patency requires comprehensive surveillance and timely repeat intervention.

Stents

Stents have been used in the extremities to correct inadequacies or complications of balloon angioplasty, including dissection, acute or chronic occlusion, significant residual gradients, and restenosis (21-26). The distal lesions of the femoropopliteal circulation are known to be more difficult to treat than proximal lesions, and stent placement in this region has recently been compared to angioplasty alone (27). In this study, 154 limbs in 141 patients (mean age 67 years) were randomized to angioplasty (n = 77) or angioplasty and Palmaz stent implantation (n = 77). The majority of the patients had intermittent claudication (n=108), and chronic critical limb ischemia was seen in the remainder. In the angioplasty group, initial technical success was achieved in 65 of 77 limbs (84%) as compared with 76 of 77 (99%) limbs in the stent group (p = 0.009). Overall, major complications were seen in 6 patients: 4 in the angioplasty group, and 2 in the stent group. Hemodynamic and clinical success at one and two years in the angioplasty group were 72% and 65% as compared with 77% and 65% in the stent group (p = .26). The cumulative one- and two-year angiographic primary patency rates were 63% and 53%, respectively, for both groups. The secondary one- and two-year angiographic patency rates were 86% and 74% in the angioplasty group, respectively, and 79% and 73% in the stent group (p = .50). The authors concluded that stent placement in this group of patients with distal lesions improved primary success but not long-term outcome.

Endoluminal Grafts

Although ELG technology has found considerable use in the treatment of abdominal aortic aneurysms, it is employed far less frequently in smaller vessels. Stent grafts allow percutaneous exclusion of isolated iliac aneurysms, iatrogenic perforation, rupture, and arteriovenous fistulas, but the incidence of these lesions is fairly low. Some investigators are also using ELGs to treat atherosclerotic disease in iliac arteries. (28-32). Indeed, grafts fashioned from Palmaz stents and polytetrafluoroethylene (PTFE) have been used successfully, (29-31) with primary and secondary patencies of 89% and 100%, respectively, at 18 months (29). Such grafts have been particularly useful in treating patients with iliac artery aneurysms. Though aneurysmal disease is rarely associated with critical limb ischemia, Figure 2 illustrates a situation in which it is a likely etiology, and Figure 3 documents ELG placement.

Treatment with ELGs in a series that included patients with limb-threatening iliofemoral occlusive disease (32) yielded cumulative primary and secondary patency rates at one year of 85% and 95%, respectively, and the limb salvage rate was 95%. More recently, the safety and efficacy of an endoluminal prosthesis designed specifically for treatment of peripheral arterial occlusive disease was studied in 127 patients with

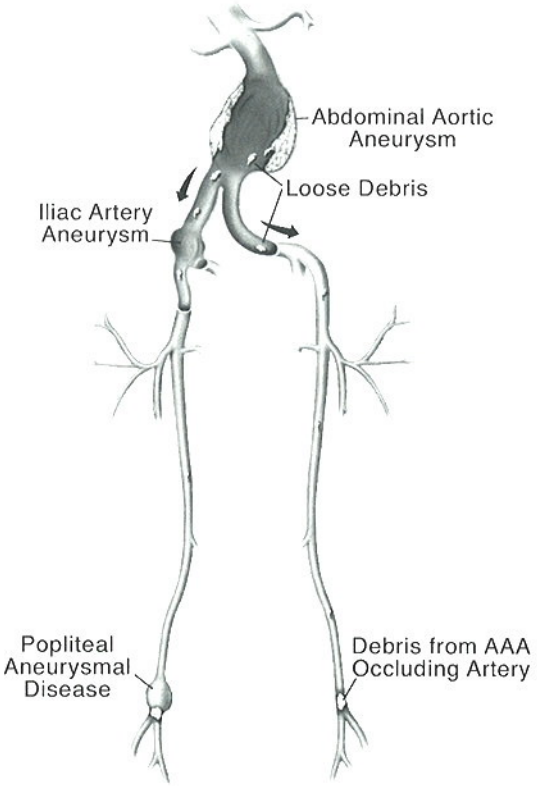

FIGURE 3

Endoluminal grafts have been used to prevent and to treat aneurysmal lesions in which the occlusion or embolization is related to critical limb ischemia.

symptomatic disease of the iliac (61 limbs) and femoral arteries (80 limbs) (33). Acute technical success was 100%, and late restenosis or reocclusion was observed in 5 iliac and 14 femoral arteries within the first year. Primary patency rates in the iliac arteries were 98% and 91% at 6 and 12 months, respectively, and in the femoral arteries, they were 90% and 79%. Although these results are promising, the data are currently insufficient to support routine use of ELGs because the devices are expensive and require placement by an operator experienced in their use.

Discussion

Successful intervention with angioplasty or other surgical or endovascular techniques is associated with significant and persistent improvements in quality of life in patients with lower extremity arterial disease (34,35). But the difficulty in deciding what treatments are most appropriate in each clinical setting remains. While a variety of therapies may result in successful revascularization, there is no universally accepted approach to treatment, probably because there are so many factors that affect outcome in patients with critical limb ischemia. Nevertheless, it is clear that as one approaches the arterial pathologies from the iliac to the popliteal, the outcome of surgical or endovascular intervention becomes less favorable below the inguinal ligament (6).

The treatment of acute and chronic disease states may be decidedly different – even when both share a common feature in their threat to limb survival. At present, angioplasty remains a valuable tool in the treatment of critical limb ischemia. There are a variety of techniques, including subintimal and laser angioplasty, stents, and ELGs, that have application in the lower extremities. Unfortunately, we are still unable to predict outcomes with specific treatments in any systematic way. There is a need for clinical trials that standardize entry criteria, incorporate strict intent-to-treat rules, and evaluate the level of technical failures in a more reliable fashion. Until the results of such trials allow us to better evaluate different treatment strategies, the interventionist must rely largely on anecdotal data and clinical judgment in choosing an appropriate course of action for patients with critical limb ischemia.

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Mechanical Thrombectomy and Atherectomy Procedures

Luciano Battaglia, Roberto Bartolucci, Lorenzo De Medici

Atherecthomy is defined as excision and removal of obstructive material, a concept introduced by Simpson (1).

The first directional atherectomy procedure was performed in 1985 by Sympson (1) in a superficial femoral artery using a peripheral atherectomy device, which realised on excision and tissue removal.

This initial experience demonstrated the safety of directional atherectomy for peripheral vascular occlusive disease (2).It was approved in U.S.A. in 1987. This device was then adapted for coronary procedures and this directional coronary atherectomy device was approved in 1990 as the first "non balloon percutaneous coronary interventional device"..

In 1987 Kensey (3) presented the Kensey rotational ablation atherectomy catheter that was launched in Europe in the early 1990s under the TRAC- Wright™ name. The device was aimed at treating calcified and thrombosed lower leg arteries.

In contrast, Wagner and Starck (4) designed the transluminal extraction-endarterectomy catheter to cut and aspirate atheroma and debris in 1989, this device was approved for peripheral vascular disease, and in 1992 for revascularization of saphenous vein bypass grafts and coronary arteries. Many other devices have been proposed during the last ten years.

TABLE I
Available treatments in acute vascular obstruction due to in situ thrombus formation or migration

√ Surgical balloon thrombectomy (Fogarty's catheter)
√ Catheter directed pharmacological therapy
√ Percutaneous mechanical thrombectomy

TABLE II
Complications with Fogarty catheter (5,6)

√ Atherosclerotic plaque migration
√ Distal thrombus embolization
√ Perforation and intimal trauma that promote intimal hyperplasia or rethrombosis

TABLE III
Limits and complications with catheter directed pharmacological therapy

Limits
- Chronicity of the lesion
- Composition of the plaque
- Location of the thrombus

Complications
- Hemorrhage
- Distal embolization

TABLE IV
Thrombectomy devices size range and compatibility with guidewire

	Size Range	Compatibility with guidewire
Trac-wire	5-9 Fr	no
Amplatz	5- 9 Fr	no
Hydrolyser	< 5 Fr	yes
Oasis	< 5 Fr	yes
Rotarex	8 Fr	yes

TABLE V
Classification of percutaneous mechanical thrombectomy devices (17)

√ Devices based on the recirculation and trapping of the clot induced by high-speed rotation of an impeller or basket, creating a vortex effect as a bender; (7,8,9,10)

√ Devices based on retrogradely oriented high-speed fluid jets, creating a negative effect (The Venturi effect), allowing the recirculation and passive evacuation of the fragments; (11,12)

√ Nonrecirculation devices, with concomitant suction using either a rotating recessed propeller (13,14) or rotating cutting blades (15) and aspiration via a roller pump or any other suction modality (16);

√ Devices using ultrasound energy for selective ablation of thrombus.

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TABLE VI
Related problems with percutaneous mechanical thrombectomy devices

√ Vascular injuries
√ Hemolysis
√ Residual thrombus
√ Distal embolization
√ Elevated cost
√ Complexity of manipulation

TABLE VII
Expected Features with percutaneous mechanical thrombectomy devices (18)

√ Ability to remove a large amount of thrombi with limited risk of embolization
√ Compatibility with a guidewire in order to avoid parietal lesions
√ Simplicity of use within a short intervention time
√ Ability to treat both acute and subacute occlusions
√ Low manufacturing cost

Percutaneous mechanical thrombectomy devices and their caratheristcs

Acolysis System™ (Angiosonics)

This system uses ultrasound to dissolve the thrombus. Two catheter are aviable: one for coronary applications and the second for peripheral arteries such iliac, femoral popliteal and crural.

The system is comprises a single – use disposable, which are 7Fr – introducer sheath, a 0.018" guide wire and the catheter probe.

The coronary device is thinner (1.65 mm diameter) than peripheral device (2.2 mm diameter).

The reach for the peripheral device is 78 cm, the coronary device has a reach of 141 cm.

This device breaks thrombus of various age, not just fresh thrombus.The whole procedure takes only a few minutes.

Aegis Vortex™ System (Kensey Nash)

The complications registered with the original TRAC-Wire catheter (3) spinsero to redevelop the device.

The actually device has a guide wire for getting calcified lesions. The wire has a balloon, which when inflated prevents the emboli caused by high-speed rotating catheter tip (150,000 RPM creating the vortex) The three part system comprises the drive unit, the 5Fr catherectomy catheter and the balloon guide wire. The CO2 filled balloon inflates to up 5mm.

Angiojet™ Rheolytic thrombectomy System (Poissis medical)

It has been developed mainly for coronary work but can also used to clear thrombus in dyalisis shunt. This is an over-the wire catheter, which creates circulation of saline solution,which carries away the thrombus.It works by the Bernoulli principle and is literally sucking the thrombus out the vessel. There are three components: a drive unit, which generates the pressurised saline solution, feed.

The second component is a pump set, which is a single used dedicated disposable used with the drive unit.

The third component is the over-the-wire catheter which reaches 140 cm. and has a 5Fr tip size and works with an outer guiding catheter of 8 Fr and 0.014" to 0.018" guide wire.

Arrow Trerotrola PDT™ Percutaneous Thrombolytic Device (Arrow International)

The device is aimed at clearing thrombus in venous and arterial peripheral vessels in the arms and in the legs, and is used to salvage grafts.

It is composed by two parts: the first, a hand –held drive device and a catheter which carries a saline feed and at its distal end it opens out a wire snare type basket which works like a food blender.

Flexi-cut™ (Guidant)

Cutting debulking system for small for small vessels work. It is has been developed for coronary vessels between 2.5 mm and 4 mm. Its reach is 134 cm. and it uses an 8Fr guiding catheter to get to the site.

The cutting mechanism is a Titanium Nitride coated cutter, which sits inside the distal end of the catheter. At its window arc it has a plunger which pushes the thrombus into the cutter.

Oasis Thrombectomy Sistem™ (Boston Scientific Medi-Tech)

Hydromechanical thrombectomy device in wich a central guide wire is used to guide the catheter tip, which has two lumen that combine to deal with the thrombus removal. The first lumen has a hooked catheter within it and this carries the saline flush fluid.

The second is a discarge port on which jet from the hooked catheter is focused.With a slow pushing movement the thrombus is broken up in the water jet and flushed away from the site.

It is intendened for recanilising limbs and also for clearing thombus in dyalis unit.

Rescue™ (Boston Scientific SCIMED)

Device developed for intracoronary thrombus removal. It is uses a vacuum to break clots into small particles, which are withdrawn into collection bottle.

The catheter part of the system comprises a 4.5F polyethylene 30 cm. monorail catheter. To develop the vacuum a pumping produces one atmosphere. The idea behind the device is to clear the fresh thrombus and then use something else to recanilise the vessel,

Rotablator™ (Boston Scientif SCIMED)

Rotational atherectomy device. It was focused at coronary vessel treatment many years ago after a brief experience in the peripheral vascular domain. The current system used a diamond rotational egg-shaped abrading system, which rotates around the guide wire at high speed.

It is kept in a central position by a central guide wire which come in three types which vary in stiffness (Rotawire Floppy, floppy Gold and Extra support). It has a foot pedal for controlling the speed, which is shown on a small console.

Rotarex™ (Straub Medical)

The device is based on the presence inside the whole length of the catheter of a coated stainless steel spiral that rotates at 40,000 rpm when the catheter and motor drive are connected by a magnetic clutch., resulting in 80,000 cut/minute At the tip of the 8Fr catheter, the spiral communicates with the vessel lumen through two oval slits.

The high rotational speed creates a negative pressure (43.5 mmHg) at the catheter distal side holes which brings the occlusion material in contact with the spiral; the fragments are transported by the spiral to the proximal sideport and discharged into a plastic bag.No additional suction is required.. The transport of the removed material is done exclusively by the rotating spiral The spiral allows the passage of a 0.020 inch guidewire. The catheter is for one-time use, while the motor drive and the connecting cable to the electronic control unit can be sterilized. (18,21)

Ultra™ Cutting Baloon (IVT)

These systems come in several sizes ranging from 2Fr to 4Fr when inflated and are fed over a 0.014" guide wire.

The microblades, of which there are three or four, are 10 mm or 15 mm in length.

The device has reach of 140 mm and its intended area of appliction is oartoostial lesions, small vessels, highly resistant lesions and in-stent restenosis.The blades are protected in a fold until balloon inflation. The device is inflated at 6 to 8 atmosphere.

Material and Methods

During a 18 months period, between June 2000 and December 2001 we have treated a total of 22 lesions in 21 patients with the use of percutaneous transluminal rotational atherectomy device (Straub Rotarex) ™.

Twenty patients were male (95.2%), and one (4.8%) was female with a mean age of 72,5 years (range 65-82). The patients were affected by chronic occlusion of the iliac, superficial femoral artery, popliteal artery, tibial vessels and in only one case by a subacute distal bypass obstruction. (Tab X)

In this case there was a thrombosis of previously PTFE femoro-tibial bypass and in 21 (95.5%) case there was a chronic occlusion.

In the case of the iliac artery steno –obstruction the patient was affected by dilatative cardiomiopathy and in program for heart transplant.

Fourtheen patients (66,7%) suffered from critical leg ischemia according to TASC criterias (19) and 7 patients (33,3%) suffered from peripheral arterial occlusive disease (PAOD) -advanced stage II (intermittent claudication).

The diagnosis was established by clinical examination, Doppler pressure recordings, photopletysmography, color duplex scan, digital subtraction angiography. An arteriography was performed via the common femoral artery in all patients before the procedure to determine the caratheristics of the lesions, to document the collateral circulation and the most appropriate treatment.

The extimated age of the lesions was between 6 days (subacute obstruction of femoro anterior tibial bypass graft) and more than 3 months (mean time).

The mean length of the occluded segments was 3cm (range 1 - 8 cm)

Laboratory examinations including: hemoglobin, hematocrit, coagulation parameters, both and 24 hours before atherectomy.

In only procedure (4.5%) was performed a balloon dilatation after the percutaneous mechanical thrombectomy. (iliac artery) No other surgical procedures was performed in any case.

The rotarex catheter was introduced percutaneously in 19 procedures (86.4%), and by open groin surgery in 3 (three) procedures (13.6%).

In case of occlusion, the lesion was first recanalysed by a guidewire. The atherectomy catheter was threaded

over the guidewire. One centimetre proximal to the upper end of the stenosis or occlusion, the catheter was activated by the foot switch and advanced through the lesion in gentle forward and back movements under fluoroscopic control. The continuous suction of blood and occlusion material into the reservoir bag was observed. After the catheter passed the stenosis or occlusion it was withdrawn in the proximal femoral artery and angiography was repeated. The number of catheter passes and the volume of aspirated blood were recorded.

The end of the procedure was based on angiographic appearance.

A technical success was defined as a post-procedural residual stenosis less than 30% at angiography or a pressure gradient less than 5 mmHg.

The average time of the atherectomy procedure was 60 minutes, with a range 20 - 75

Average rotary time of the atherectomy catheter was 10 minutes ranging 7- 15

A mean of 3.5 catheter passes (range 1-5) were require to dilate the arterial lumen

All patients received either antiplatelet drugs and anticoaugulant therapy immediately after the intervention and antiplatet therapy at demission from hospital. The patients were descarged from hospital in second post-operative day in 15 cases.(71.4%) The patients were assessed by duplex sonography after 48 hours (pre-demission), 1 month, 3 months, 6 months and 1 year after the procedure.

TABLE VIII
Indications for treatment with rotarex system as thrombectomy device

√ Thrombotic lesions
√ Acute and subacute occlusions

TABLE IX
Indications for treatment with rotarex system as atherectomy device

√ In-stent restenosis
√ Ulcerated, embolic, eccentric, ostial, long lesions (either stenosis or occlusion)
√ Bifurcated lesions
√ Calcified lesions

Preliminary Results

According to other group (20) the patients may be classified in five classes of result.

Intraoperative angiographic success, in-hospital success, late success, immediately failure and late failure (Tab. XI).

TABLE X
Types of the lesions in present series

Lesion site	N° cases	Comment
External iliac artery	1	atherectomy
Superficial femoral arteries	17 (1 bilateral)	atherecthomy
Popliteal arteries	1	atherectomy
Anterior Tibial artery	1	atyherectomy
Thrombosed Femoro-tibial bypass graft	1	thrombectomy

TABLE XI
Classes of result (20)

√ Intraoperative angiographic success
√ In-hospital success
√ Late success
√ Immediate failure
√ Late failure

According to these criterias, in present series atherectomy was technically successful (intraoperative angiographic success) in 20 (95.2%) of 21 atherectomy procedures. Thrombectomy, only one case, was technically successful.

In hospital success was observed in 20 procedures (90.9%) Immediate failure was observed in 1 procedure (4.5%), Late failure was observed in 2 procedures (9%)

In only one procedure we have observed a rupture and subsequent thrombisation of the superficial femoral artery (4.5%). (immediate failure)

We have observed no distal embolization.

A small non – occlusive dissection was observed in 2 procedures (9%). No treatment was performed in these cases.

Blood and dedritus were aspirated at 1.1 ml/sec; the total aspirated volume ranged from 40 to 110 mml depending on the length and consistency of the lesion.

Blood loss was noted in all patients with a mean decrease of hemoglobin value of three point at least, in the immediate post-operative period (48 hours). Howerver, only one patients (4.7%) required blood transfusion (one unit).

In only 1 procedures PTA was performed and no stent was placed.

Ankle / brachial index improved from 0.4 preinterventionally (mean value) to 0.6 after interventionally (mean value).

At the follow-up at 18 months (range 3–18 months) we have observed 2 major amputations (9%), and 1 non related death (cardiac complications) (4.7%).

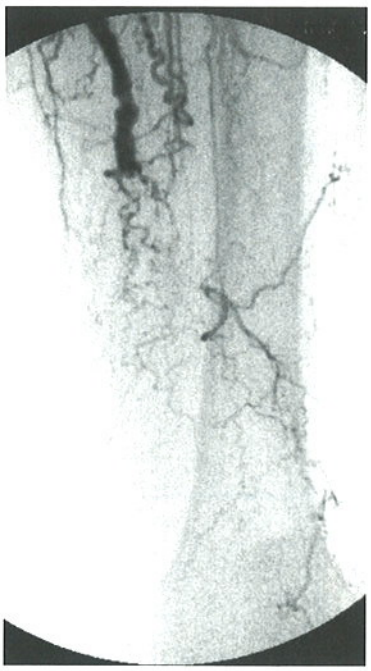
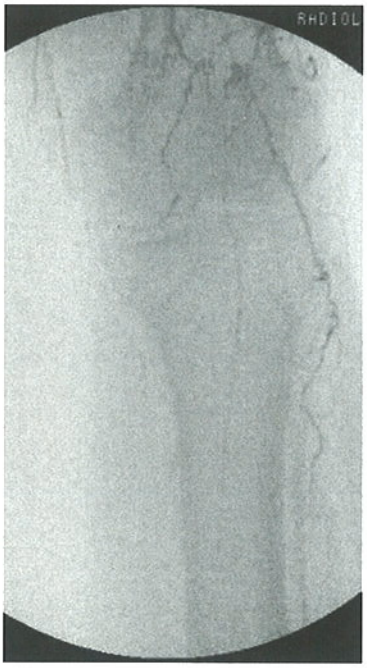


FIGURE 1



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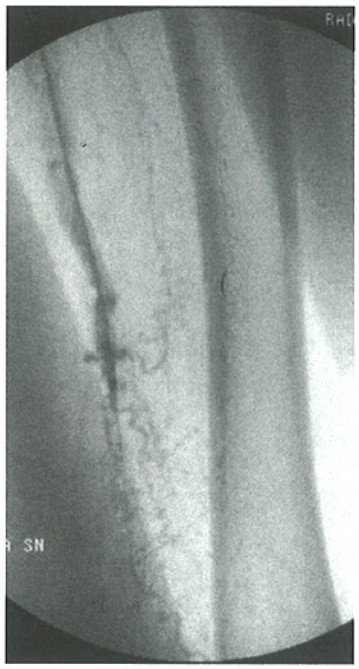

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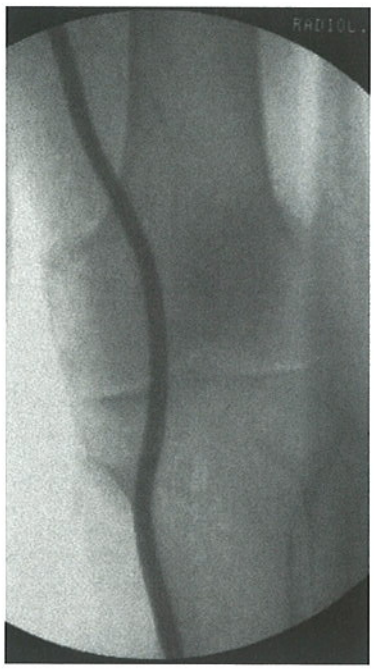

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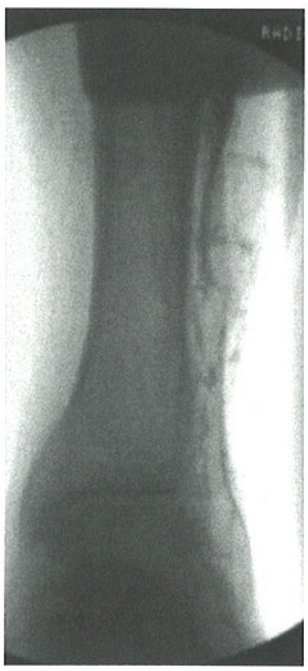

FIGURE 5

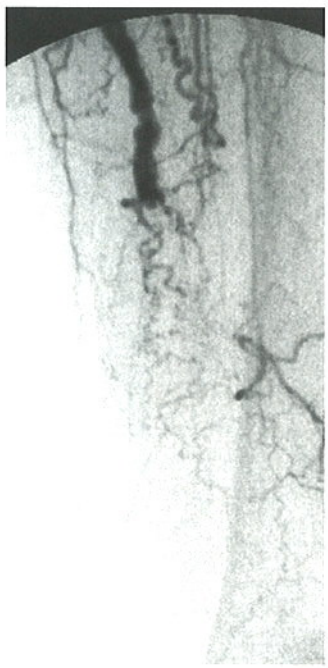

FIGURE 6

FIGURE 1-6
Recanalization of thrombosed femoro – anterior tibial PTFE bypass graft

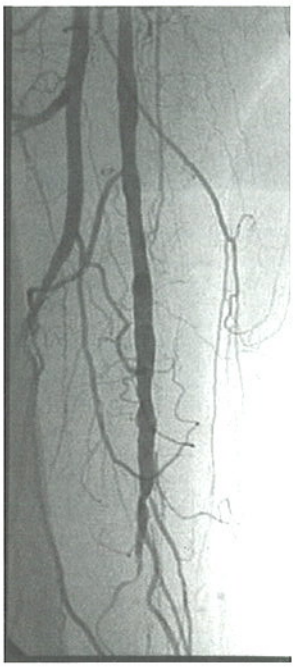

FIGURE 7

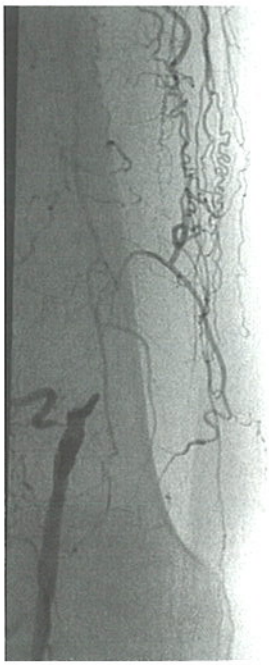

FIGURE 8

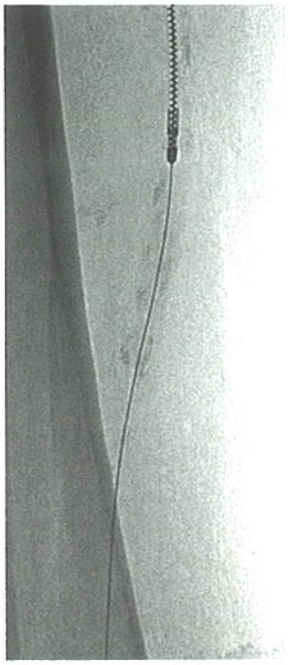

FIGURE 9

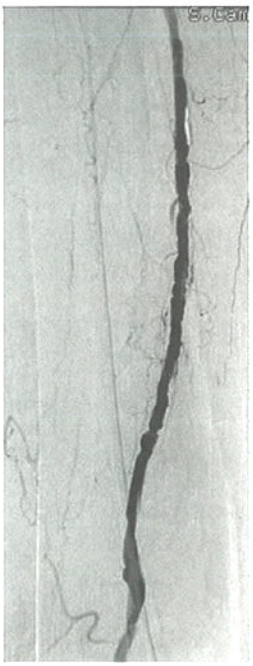

FIGURE 10

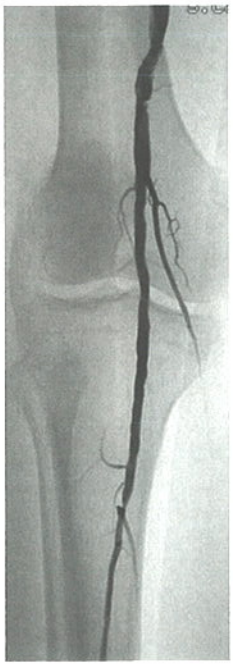

FIGURE 11

FIGURE 7-11
Recanalization of obstructed superficial femoris artery (Hunter's canal)

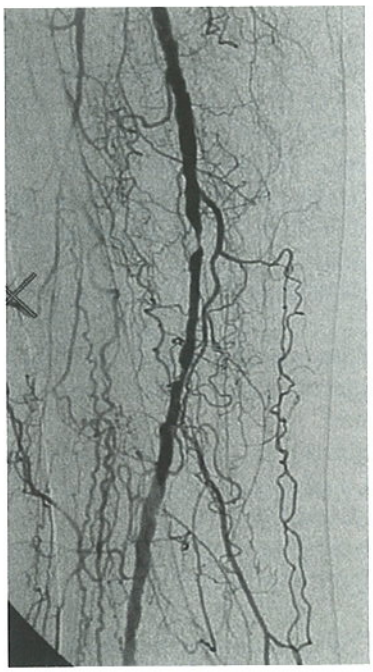

FIGURE 12

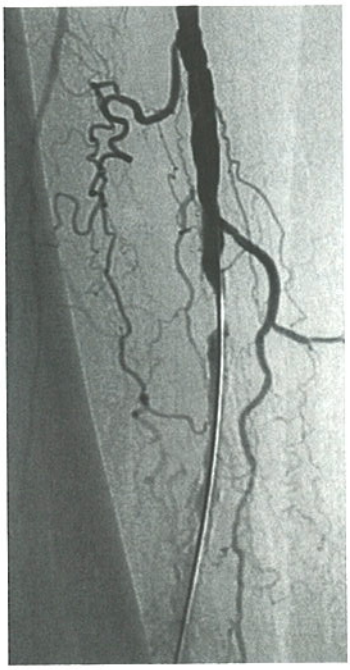

FIGURE 13

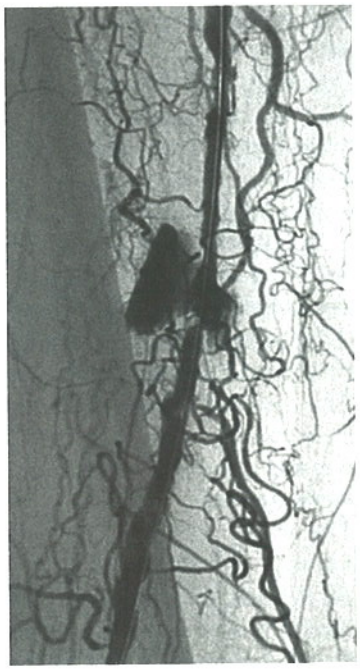

FIGURE 14

FIGURE 12-14
Recanalization of obstructed superficial femoris artery complicated from immediately rupture

Discussion

In the last decade great effort have been made to provide an alternative to fibrinolysis and surgical thrombectomy in the treatment of vascular thrombosis.

Percutaneous mechanical thrombectomy techniques have been introduced in an attempt to decrease the risks and costs associated with pharmacologic thrombolysis, particular the significant time required and hemorrhagic complications associated either thrombolitic.

The efficiency of a percutaneous mechanical device can be defined as the percentage volume of thrombus cleared or fragmented into sufficiently small particles during the treatment, thus reducing the risk of distal embolization.(18).

Many of these device are effective in clearing fresh thrombi, especially in arterial and hemodialysis grafts; their effectiveness decreases with age of thrombi and their aderence to the vessel wall.

Since many vessel occlusions are "acute on chronic" thrombosis, an ideal thrombectomy device should have the potential to remove organized thrombus, it should track over a guidewire in order to prevent vessel injury and it should transport the removed material to the outside without the risk of embolization.

A useful parameter for the assessment of the efficacy of a thrombectomy device is the radial expansion coefficient, the ratio of the lumen recanalized by thrombectomy to the catheter diameter. In vivo the radial expansion coefficient depends on the composition of the occlusion material.. It is about 2 in fresh thrombi but drops to 1 in solid material, which means that the reopened lumen corresponds to the diameter of the catheter.

The maximum acceptable size of distal embolic particles depends on the specific target circulation, and particles larger than 100 micro m are usually considered significant in the peripheral arteries while only 1000 micro m particles are considered significant in the pulmonary arteries.

If distal embolization is significant, additional thrombolysis can be discussed, although this attitude is in contradiction to the rationale of percutaneous mechanical devices which avoiding the thrombolitic therapy.

Compared with other thrombectomy devices the rotarex system catheter removes not only loose thrombus but also solid occlusion material (21)

The catheter pass the calcificated plaques without abrading them. Therefore, an adjunctive percutaneous transluminal angioplasty after thrombectomy is often advisable to eliminate residual stenosis.

The vast majority of percutaneous thrombectomy device range in calibre from 5 to 9Fr. And some of them can not be handled over a wire; thus they lack torque

control and have poor stability. Device exploiting the Venturi effect have the advantages of small size and compatibility with a guidewire.

The actually large caliber of the Straub Rotarex catheter limits its use in the treatment of small vessels. Nevertheless, its compatibility with a guidewire lessens the potential risk of vessel injuries

Traumatic hemolysis can occur with many percutaneous thrombectomy devices, especially those using high-speed rotation or high-speed fluid jets.

After prolonged use of this type of device, significant hemolisys was described.(21).

The rotation speed of the Straub Rotarex device is much slower at the procedure time compared with other high-speed rotational percutaneous mechanical thrombectomy devices.

The speed rotation is exponentially linked to the importance of hemolysis.

All devices that comprise either an active or passive aspiration system pose a potential risk of blood loss. Precise monitoring of fluid volume balance is thus critical, even though the application time of the mechanical thrombectomy device should be short.

Conclusions

The new mechanical catheter device represents an important procedure among endovascular tools with good patency rates in anterograde recanalisation of acute and chronic thrombotic vessels occlusion.

The Rotarex system can be used treating both acute thrombotic lesions and chronic occlusion of vessels, as demonstred in our experience.

This is safe and feasible especially in arteries with 4-5 mm diameter.

However, this procedure permits also a combined endovascular/surgical approach or, if necessary, an open surgical reconstruction.

When used in a combined approach, the Rotarex system may improve the outflow of vascular bed providing for an adequate distal reconstruction.

Our preliminary results may suggest a moderate optimism but we remember that this procedure is performed in selected patients.

Actually, the limits of this device are represented in the availability of a single catheter of 5 Fr diameter and in the remarkable experience requested with this particular endovascular procedure.

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