Symposium: Clinical Research

Endovascular interventions of the femoro-popliteal disease in the elderly

Gianluca Rigatelli, Paolo Cardaioli, Fabio dell’Avvocata, Massimo Giordan, Luca Zattoni

Department of Cardiovascular Diagnosis and Endoluminal Interventions Unit, Rovigo General Hospital, Rovigo, Italy

Abstract In the last few years the treatment of superficial femoral artery (SFA) occlusive disease has undergone greater changes in management including more aggressive endoluminal therapy, especially in the elderly patients who are at high risk for extra-vascular comorbidities from the surgical approach. While acute and chronic arterial limb ischemia is the conditions which the interventional cardiologists frequently encounter, the elderly population represents special problematic clinical and anatomical setting due to heavy calcification and poor distal run-off. Arterial thrombolysis, rheolytic thrombectomy, mechanical thrombectomy, laser angioplasty, cryoplasty, and new flexible long stents are some of the promising techniques to improve the technical and clinical outcomes in these elderly patients. (J Geriatr Cardiol 2007;4:80-7.)

Key Words peripheral vascular interventions; systemic atherosclerosis; stenting; angioplasty

Introduction

Chronic lower extremity ischemia secondary to atherosclerotic disease accounts for more than 400,000 hospitalizations in the United States each year and has been associated with a 20% annual mortality, mostly from cardiovascular events.1,2 For patients with critical limb ischemia (CLI) presenting with a nonhealing ulcer or rest pain, surgical bypass grafting has been the gold standard, with a 5-year limb salvage rate of 80%.3,4 In contrary, the main treatment of intermittent claudication has been traditionally medical, with aggressive risk factor control, exercise training, and pharmacologic management while surgical bypass has been reserved for patients who fail the medical conservative approach.5,6 Intrainguinal bypass can be performed safely with a low perioperative mortality; however, because of pre-existing comorbid conditions, local and systemic postoperative morbidity approaches 30% in this patient population.7-9 Furthermore, patients often experience an extended recovery interval with more than 50% of patients reporting a return to their preoperative functional status by 6 months.10

In the last few years, the treatment of superficial femoral artery (SFA) occlusive disease has undergone a shift in management within these paradigms to include more aggressive endoluminal therapy. Reports from the 1980s and 1990s suggested that SFA angioplasty be an adequate short-term intervention, but that long-term patency was poor. Four randomized trials11-14 have shown that primary stenting added no benefit. However, stent design has continued to evolve since the completion of these randomized trials.

General indications

Invasive methods of treatment (percutaneous or surgical revascularization) should be reserved for patients with lifestyle disabling claudication, ischemic rest pain, or nonhealing ischemic ulcers and gangrene. Patients with popliteal and below-knee occlusive disease often present with limb-threatening ischemia. They are usually elderly and have several comorbid conditions, such as diabetes and coronary artery disease, that increase the surgical risk. Lesion type based on the TransAtlantic Inter-Society Consensus (TASC) criteria will also effect patency, with TASC A appearing to be very suitable for endoluminal therapy, whereas TASC D lesions are most suitable for bypass.15 Optimal therapy for TASC B and C lesions remains undecided (Table 1).

Peripheral vessels anatomy and pathology

Two types of arteries have to be distinguished: the muscular and the elastic ones. The difference between them is important to understanding the pathology and the
The spectrum of femoropopliteal disease includes not only the chronic occlusive disease, but also less often the occurrence of acute ischemia (Fig. 1, 2), due to plaque embolism or iatrogenous maneuvers such as compressive bandage after invasive catheterization. This phenomenon occurs through a mechanism mediated by chronic arterial lesions.

Intraarterial thrombolysis is an alternative to balloon embolectomy in the treatment of acute lower limb ischemia. It has a complete success rate of 69% to 86%, with primary patency rate ranging from 75% to 87% at 2-years. Despite these results, hospitalization costs seem to be higher than in primary surgical approach because of the need for subsequent surgical revascularization after failure of percutaneous intervention in native femoral artery or bypass grafts. Recently, reteplase was shown to be a valid alternative to urokinase with a technical success rate of 87% and a major complication rate of 16%; a reduced dose of thrombolytic drugs should be taken into account when dealing with elderly patients. The percutaneous treatment includes thrombus aspiration catheter or rheolytic thromboembolectomy. The latter seems to be the most attractive technique with a technical success rate ranging from 88.4% to 90% and primary patency rates of 79% and 60% at 6 months and 2 years, respectively. The thrombectomy technique is illustrated below.

The thrombectomy technique

The technique includes the controlateral retrograde or ipsilateral antegrade femoral approach and the passage of a soft .035” guidewire through the occlusion. In case of acute thrombosis, intraarterial thrombolysis or antiplatelet drugs (tirofiban, epifibatide, etc) should be infused through a side hole catheter. In case of subacute thrombosis, a large lumen 6 F guiding catheter connected with a 50ml syringe should be passed over the wire aspirating fresh thrombus. To optimize the results of rheolytic thrombectomy a peripheral 6F device such as the Angiojet (Possis Medical) can be used for 3-6 passages (maximal blood volume 200-300 ml to avoid hemolysis in elderly patients) to completely restore the flow. An angioplasty balloon may be also used in case of resistant

Table 1. Morphologic stratification of femoropopliteal lesions

<table>
<thead>
<tr>
<th>Lesion type</th>
<th>Description</th>
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<tbody>
<tr>
<td>Type A</td>
<td>Single stenosis up to 3 cm long, not at the origin of SFA or distal popliteal artery</td>
</tr>
<tr>
<td>Type B</td>
<td>Single stenosis or occlusion up to 10 cm long not involving the distal popliteal artery</td>
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<tr>
<td></td>
<td>Heavily calcified stenosis up to 3 cm long</td>
</tr>
<tr>
<td></td>
<td>Multiple lesions each less than 3 cm long (stenoses and occlusions)</td>
</tr>
<tr>
<td>Type C</td>
<td>Single or multiple lesions in the absence of continuous tibial run-off to improve inflow for distal surgical bypass</td>
</tr>
<tr>
<td></td>
<td>Single stenosis or occlusion 10 cm long</td>
</tr>
<tr>
<td></td>
<td>Multiple stenoses or occlusions, each 3–5 cm, with or without heavy calcification</td>
</tr>
<tr>
<td>Type D</td>
<td>Complete common femoral artery and/or superficial femoral artery occlusion or complete popliteal and proximal trifurcation occlusion</td>
</tr>
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Clinical chronic critical arterial ischemia

Clinical chronic femoropopliteal ischemia is the most common condition seen by interventional cardiologists. In general, interventions in the femoral and popliteal arteries are discussed together because of similar antegrade approach, results, and types of complications. The role of angioplasty and conventional stenting in the treatment of atherosclerotic disease in the femoropopliteal arteries has been extensively evaluated in randomized trials.\textsuperscript{11-14} Whereas indications for percutaneous interventions at the iliac level are well defined, there are more debate about indications for interventions in the femoropopliteal level, where the long-term results are not always favorable. The failure rate of femoropopliteal catheter-based procedures correlates with the type (stenosis vs occlusion), the location (femoral vs popliteal) of the lesion treated, the status of the distal run-off (focal vs diffuse occlusive disease), and the severity of limb ischemia.

At this present time, stenting is the most preferred method of treatment. The coil stents have been suggested for soft femoral lesions\textsuperscript{28,29} and the popliteal area due to the flexibility of the stent to conform to the curve of the arteries. It has a restenosis rate of 14.4\% and a primary patency rate of 84.7\% at 4 years.\textsuperscript{30} The Nitinol stents are preferred in segment near the hip and knee joints, while the bare-metal stents are best for the fibrocalcific plaque due to their high radial force.

In an attempt to improve the patient’s outcome, some investigators have begun to evaluate the duplex ultrasound-guided angioplasty and the use of stent-grafts and alternative forms of endovascular procedures, such as thermal laser angioplasty, vibrational angioplasty, cryoplasty, and new atherectomy devices. The use of duplex ultrasound-guided angioplasty in patients at high risk for contrast induced complications showed a lower technical success and similar 12 month patency rate to standard angioplasty.\textsuperscript{31} The stent graft technology has been proven effective in the short-to mid term evaluation, especially for the short occlusions with a primary patency rate of 49\% to 73.2\% and an re-obclusion rate of 28.6\% to 72\%\textsuperscript{32,33} at 1 year. The thermal laser angioplasty technique has been proven to be effective, with successful recanalization of the superficial femoral artery in 80\% of cases and a primary patency rate of 50\% at 1 year.\textsuperscript{34} However, this technique was plagued with a high rate of perforation and acute thrombotic occlusion. It has also been suggested that vibrational angioplasty, using coronary equipment, improve the recanalization rate in long chronic femoral occlusion with a 100\% technical success rate and acceptable patency at 9 months.\textsuperscript{35} Moreover, an interesting and promising technique seems to be the cryoplasty. In this technique, the angioplasty balloon is inflated with pressurized nitrous oxide which cools to a temperature of minus 10 degrees Celsius, freezing the plaque and inducing apoptosis. The preliminary results of the first human trial demonstrated a restenosis rate of 12\% and a reduction in the rate of meaningful dissection to around 6\% when compared to 40-45\% of standard percutaneous transluminal angioplasty (PTA).\textsuperscript{36} Finally, two rotational atherectomy devices, the Rotarex catheter (Straub medical AG, Waing, Switzerland) and the Xtrak have shown encouraging early results.
results in recanalizing acute, subacute, and chronic femoropopliteal occlusions. Larger and longer follow-up studies are needed to assess their real effectiveness.

Femoral bifurcation lesions as well as any other lesions at the bifurcation, regardless of their localization (i.e., coronary, renal, iliac, femoral and tibio-peroneal trunk) should be especially approached. The femoral bifurcation is the most ambiguous and challenging arterial lesion from a percutaneous perspective. The first reason is that the superficial location exposes the stent to external compression. The second reason is that an incidental iatrogenic injury (e.g., occlusion) to the deep femoral branch may threaten the function of the lower extremity because present and future collateral circulation to the lower limb depends on the patency of this branch. Consequently, surgical endarterectomy is preferred when common femoral disease extends to the deep and superficial femoral arteries, because the bifurcation may easily be surgically accessed without significant risks. In the elderly patients with reduced mobility, stenting of the common femoral artery can be successfully performed with short balloon-expandable or nitinol self-expandable stents (Fig. 2).

The techniques

Two techniques are used to recanalize a chronically occluded femoral artery: the endoluminal technique and the subintimal technique. The former is the conventional technique; through a contralateral retrograde or ipsilateral antegrade approach, the occlusion is crossed with a hydrophilic stiff guidewire inside a hydrophilic catheter such as the Terumo Glidecath. Then dilation with an increasing size balloon should be performed to achieve an optimal arterial lumen. A thrombectomy device such as the Rotarex device can be used to enlarge the lumen. Stents can be implanted to ensure long-term patency (Fig. 3). In complete occlusion of the superficial femoral artery, especially in heavy calcified vessels, the endovascular success rate is low. In 1990 Bolia and his associates first described the technique of percutaneous intentional extraluminal recanalization of femoropopliteal total occlusions. According to this technique, at first a stiff 0.35” guidewire was used to enter and cross the lesion in the subintimal space, then stiff angled catheter was advanced through the dissected plane and re-entered the true lumen beyond the total occlusion segment. One major limitation of this technique is the inability of re-entering the true lumen beyond the occlusion. In such case a new re-entry device such as the Outback device can be used (Figure 4). The following case report illustrates this special technique. Following a 6 Fr arterial sheath placement via the antegrade approach in the left common femoral artery, and administration of 5000 IU of heparin, an angiogram is performed to visualize the superficial femoral artery segment distal to the total occlusion. An angled 0.035-inch hydrophilic guide wire (Terumo, Tokyo, Japan), looped at its tip, is advanced with a supporting 4 Fr Bernstein catheter, in order to create a subintimal dissecting plane. Once the wire reached the subintimal space near the distal end of the occlusion, a Bernstein catheter is advanced and the 0.035” wire is exchanged for a 0.014” supportive Hi-Torque Balance Heavyweight Guide Wire (Abbott Vascular, Illinois, U.S.).

Figure 2. (A) Occlusion at the junction of common and superficial femoral artery (Left Anterior Oblique projection) and stenosis of the profunda femoral artery (B) Result after stenting of the main vessel with a Nitinol stent and kissing balloon of both vessels through the stent struts.
A monorail 2.5×30 mm balloon (AvionPlus Invatec, Roncadelle, Italy) is advanced in the subintimal plane and dilated to create the space for the device. The Outback re-entry catheter is advanced beyond the occlusion over the 0.014” wire, which is subsequently withdrawn. Under fluoroscopic guidance the device should be oriented so the “L” marker is pointed toward the lumen of the SFA and the “T” marker towards the vessel wall. Once the position is checked, the needle can be advanced to enter the true lumen. A small injection of contrast confirms the position and the 0.014-inch wire is re-advanced in the true lumen distally to the occlusion. After multiple dilations with a 3.5 mm diameter compliant balloon, a Nitinol self-expanding stent should be used for complete lesion coverage.

Problems of the percutaneous approach: stent fracture, restenosis, and reocclusion

Stent fracture is the dark side of endovascular femoral interventions. The 3-year primary patency rates of approximately 50% have been reported for PTA and first-generation stents. The early results of newer Nitinol stents appear to be more promising. The 1- and 2-year primary patency rates were 76% to 97% and 60% to 84%, respectively. However, the long-term data are lacking. An emerging concern with Nitinol stents is the frequent rate of stent fracture (≥25%) after interventions for long-segment disease. Recent studies have shown that stent fractures are associated with in-stent restenosis and with significantly lower primary patency at 1 year. Restenosis and reocclusion are...
important factors associated with suboptimal results of endovascular intervention in the femoral artery. Different strategies are being proposed. Of these, the most attractive ones are brachytherapy and implantation of drug-eluting stents. Brachytherapy with gamma-radiation, inducing positive remodeling, has been recently tested in the treatment of femoropopliteal arteries restenosis; The Vienna 2-Trial demonstrated a cumulative patency rate at 1 year of 63.6% with brachytherapy after PTA in de novo lesions compared to 35.3% with PTA alone, whereas the PARIS trial demonstrated an angiographic restenosis rate of 17.2% at 6 months and a clinical restenosis of 13.3% at 1 year. The only relevant clinical drawbacks following brachytherapy are late thrombosis or occlusion that occurred in 27%, requiring prolonged anti-thrombotic therapy.

The use of drug-eluting stents is being extensively investigated for the femoropopliteal lesions after exceptional results from the coronary circulation. Six month results of the first series using the SMART-sirolimus coated stent showed an in-stent percent diameter stenosis of 22.6% compared to 30.9% in the uncoated stent group. However, the second SMART trial failed to demonstrate a maintained benefit on long-term follow-up.

Complications

The incidence of major complications after femoropopliteal stenting versus PTA are 7.3% (0–17%) versus 4.3% (2.4–6.3%). These are mostly due to vascular access site problems, i.e., hematomas, pseudoaneurysms, and thromboembolic occlusions. Full-dose anticoagulation for patients with infrainguinal stents and stent-grafts is recommended to prevent acute thrombosis of the stented segment which can occur in up to 25% of cases within the first month of deployment. Heparin (3 000–5 000 IU) was usually given once the introducer sheath was placed. Evidence from coronary circulation supports the application of an anticoagulation regime of low-molecular-weight heparin for 2–14 days, and a combination of acetylsalicyclic acid (50–350 mg daily) with clopidogrel (300 mg starting dose followed by 75 mg daily). Postimplantation syndrome with fever and local pain complicates polytetrefluoroethylent(PTFE)-covered stent-grafts in up to 5.8%, and Dacron-covered stent grafts in up to 40% of patients.

Conclusion

Femoral artery obstructive disease remains a challenging field for all interventionalists. The elderly population represents a greater problematic clinical and anatomical setting due to high grade calcification and poor distal run-off; new stent design and new devices may help to achieve better future outcomes.

References


