Introduction
Acute ischemia of the lower limbs is a critical vascular emergency that not only endangers the affected extremity but also puts the patient’s life at risk. The prognosis strongly depends on the efficacy and safety of the initial treatment. Catheter-directed thrombolysis (CDT) and open surgery are common therapeutic modalities. However, both procedures are associated with significant mortality and morbidity rates.1

The purpose of this prospective study was to establish whether the initial treatment of acute (ALI) and subacute ischemia (SLI) of the lower limbs can be done successfully by endovascular mechanical debulking of occluded target vessels with a catheter combining atherectomy and thrombectomy, without having to use thrombolysis and/or open surgery.

Materials and methods

From April 2009 to April 2015, we prospectively and consecutively included 316 patients (184 men and 132 women; age range, 23-96 years; mean age, 70.9 years, SD 12) with ALI (202 patients, 63.9% of 316) and SLI (114 patients, 36.1% of 316) referred to our interventional angiology clinic. The ALI group included 146 participants (72.3% of 202) as classified clinical category IIB (immediately threatened) and 56 participants (27.7% of 202) as classified clinical category IIIA (marginally threatened).2 According to the Rutherford classification for chronic limb ischemia,2 41 patients with SLI were included in category 4 and 4 patients in category 5 (mean 3.8, SD 0.7).

A mechanical debulking device (Rotarex, Straub Medical AG, Wangs, Switzerland, fig. 1) was used to recanalize the target vessels: femoropopliteal artery bypasses in 195 patients (62% of 316). These were not managed by the Rotarex in 13 patients because of femoropopliteal arterial segments in 21 patients, prosthetic or venous bypasses in 75 patients and aorto-tibial segments in 15 patients. Recanalization efforts were removed by percutaneous aspiration thromboembolectomy3 (PAT) and endovascular biopsy device.Anticoagulant techniques were used to treat underlying and culprit lesions (residual stenoses >30%).

Concomitant infropopliteal occlusions or significant stenoses (>50%) were present in 195 patients (61.7% of 316). These were not managed by the Rotarex because the vessel diameter was less than our threshold of 4 mm.

Results

Mean length of target occlusions was measured by the Rotarex catheter was 22.9 cm (SD, 14.8; range, 1-45) before therapy. Origin of the occlusion was thrombotic in the majority (81.0%, 256/316) of participants. The occlusion was partially or completely located in the previously implanted stents in 23.4% (73/316) of patients. Recanalization efforts were removed by percutaneous aspiration catheter on angiography before treatment.

The removal of fragmentable occlusive masses resulted in antegrade flow restoration in all target vessels. The mean percentage diameter narrowing was 38.4% (SD, 26.1; range, 0-90%) and the mean residual stent length was 3.8 cm (SD, 9.4; range, 0-40) after Rotarex debulking alone. There was no residual stenosis in 52 patients (16.5% of 316). Technical success defined as the reduction of the stenosis diameter to 50% or less after Rotarex debulking was angiographically documented in 132 patients (74.3% of 171). In 140 patients (44.3% of 316), the reduction of the stenosis diameter to 10% or less was reached with Rotarex debulking alone.

The overall technical success (residual diameter stenosis of 30% or less) was 100% after mechanical debulking and adjunctive occlusions at the technical level of the target vessel.

Before target vessel occlusions where mechanical debulking was the initial therapy, there were 195 patients (62% of 316) with additional intervention in infrapopliteal vessels for angiographically significant stenoses and/or occlusions. The mean number of patent tibial arteries (with or without angiographically significant stenoses) before therapy was 0.9 (range 0-1, SD 0.7) and the mean number of patent tibial arteries (without significant stenoses, with good pedal outflow) was 1.9 (range 0-1, SD 0.9) after endovascular treatment (p<0.001).

Early outcomes (<30 days)

With mechanical debulking, PAT and biopsy extraction as initial therapeutic techniques in patients with ALI and SLI, we did not exclude thrombolytic therapy completely. Thrombolytics were administered in 29 patients (9.2% of 316) with diffuse thrombosis in 25 (7.9% of 316) patients after Rotarex debulking and with pseudoaneurysm in 5 patients. Those adverse effects were not related to the mechanical debulking technique.

Clinically insignificant vessel perforations with the guidewire were monitored during difficult passage through infrapopliteal occlusions in 13 patients (4.1%).

Minor complications can be related to Rotarex debulking in 26 patients (8.2% of 316): extravasation from target vessels (7%) and peripheral embolization (19%). There were no treatment-related complications causing amputation.

12-month follow-up

At one-year follow-up, data were available from 199 patients (87% of 229). We have documented eight deaths (4% of 199) and 17 amputations (9.9% of 199). Amputations occurred more frequently in patients with thrombosis when compared with embolic subgroup (10.7% vs 0.0%, p=0.03).

Amputation-free survival was 86.9% in the entire group of 199 patients with ALI (202 patients, 63.9% of 316). We have documented eight deaths (4% of 199) and 17 amputations (9.9% of 199). Amputations occurred more frequently in patients with thrombosis when compared with embolic subgroup (10.7% vs 0.0%, p=0.03).

Amputation-free survival was documented by the mean ankle-brachial index (ABI) that increased from 0.13 (range: 0-0.62 SD 0.16, n=309) before therapy to 0.78 (range:0-1, SD 0.25, n=300) after treatment (p<0.001).

Clinical success was documented by the relief of acute ischemic symptoms in 182 patients with ALI (90.7% of 202). The mean Rutherford clinical category (classification of chronic limb ischemia) changed from 3.8 (SD 0.7, range, 3-5) before therapy to 1.2 (SD 0.1, range, 0-3) after treatment (p<0.001) in 114 SLI patients.

Revascularizations of deburred arteries occurred in 18 patients (6% of 316) with the need for endovascular reintervention in 9 patients. Secondary patency was 97%.

Major complications occurred in 21 patients (7.5% of 316). They included one death due to intracerebral haemorrhage associated with thrombolysis. Other serious bleedings occurred from the puncture sites (gonal hematoma in five and retroperitoneal bleeding in two patients). In total, major bleeding occurred in 8 patients (2.5% of 316). In four of them, thrombosis was applied as adjunctive technique. Thus, major bleeding complications were associated with thrombolysis in five patients (45% of 11). There was no causal association between major haemorrhage and mechanical debulking.

Three patients (0.9% of 316) underwent fasciotomy due to compartment syndrome. There were no major complications associated with mechanical removal of occlusive material alone.

Minor complications were documented in 63 patients (19.9% of 316). Peripheral embolization occurred in 40 patients (12.7% of 316), after Rotarex debulking in 19 cases (6% of 316), and after PTCA or stenting in additional 21 patients (6.6% of 316). All emboli were immediately removed by Rotarex, and/or by extraction with the endovascular biopsy device.

Extravasation from the deburred segments was detected in six patients (3.9% of 194) immediately after Rotarex action and in another two patients (0.6% of 316) after balloon dilation of residual stenoses. Injury was located in the popliteal artery (7) and venous femoropopliteal bypass (2). Extravasation was immediately eliminated by covered stents in seven patients and by glycoprotein IIb/IIIa blocking drug (10 min) in two patients.

Compartment syndrome developed in seven participants (2.2% of 316) without need for fasciotomy. Intraprocedural rethrombosis developed in previously cleaned arterial segments in 18 patients (5.7% of 316) with the need to repeat the clot removal during the same procedure. Minor clinically non-significant groin hematoma developed in 25 (7.9% of 316) patients at the puncture site with pseudoaneurysm in 5 patients. Those adverse effects were not related to the mechanical debulking technique.

Conclusions

Mechanical debulking cannot fully replace open surgery and thrombolysis in the therapy of ALI and SLI but it shifts those modalities to the category of adjunctive techniques and it should be considered as the first-line therapy whenever possible.

Literature

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