

### **PATIENTS AND METHODS**

This is a prospective study of a total of 100 diabetic patients (50 males, 50 females) presenting to our department of vascular and endovascular surgery, Kasr Al Ainy hospital, Cairo University, with critical limb ischemia, and underwent either angioplasty alone or angioplasty with stenting for infrainguinal disease along the period of 2/2013 to 1/2014.

Chronic critical lower limb ischemia was defined following the TASC II guidelines as: lower limb with more than two weeks of rest pain, ulcers, or tissue loss attributed to arterial occlusive disease. (Norgren et al, 2007)

Patients with acute ischemia were excluded from this study. Since the study was designed to examine infrainguinal interventions, patients requiring iliac intervention at the time of primary infrainguinal treatment were excluded. Patients presenting with non-salvagable limbs requiring primary major amputation, acute thrombosis, embolic occlusions, aneurysms, trauma, arteritis, entrapment syndromes, were excluded from this study.

Based on review of patients' sheets, detailed present and past medical and surgical history was obtained from all patients. This included medical history (hypertension, cardiac or renal disease, regular medications, smoking habits). This also included past history of previous interventions. Disease presentation was categorized as rest pain, minor tissue loss, or major tissue loss. Ipsilateral and contralateral palpable pulses at initial presentation were recorded.

All patients were admitted to the hospital at least for 24 to 48 hours before the procedure. Proper hydration was ensured by adequate fluid intake the

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day before the procedure. N-acetylcysteine was given in large doses 600 mg pre and post-procedurally. A loading dose of clopidogrel 300 mg was given the night of the procedure that is to be continued post-procedurally at a maintenance dose of 75 mg daily.

Procedures were performed with the patient in the supine position. An antiseptic solution (povidone iodine) used to disinfect the groin area and sterile towels were placed over the patient.

For all cases a local anesthetic (Xylocaine 2%), or epidural anaesthesia was used.

After obtaining a vascular access via ipsilateral or contralateral femoral punctures, a bolus of 5000 IU of unfractionated heparin was administered. An initial angiogram was done to determine the morphology of the lesion and the plan of treatment. Lesion location, length, presence of chronic occlusion or stenosis, TransAtlantic Inter-Society Consensus (TASC) classification, and status of the distal run-off vessels were verified.

A 0.035, 0.014 or 0.018-inch guide wire was inserted to cross the lesions either transluminally or subintimally. Balloon catheters were used for the dilatation of arteries. Stents were used selectively, if flow limiting dissection, occluding intimal flaps, or suboptimal results persisted despite repeated, prolonged balloon inflations. Vessel recanalization was considered successful when direct flow was obtained angiographically in the treated vessel with or without retrieval of distal pulsation.

Intra-procedural complications such as vessel recoil and spasm, dissection whether flow limiting or not and the need of treatment were all reported. In

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cases of vessel spasm Tridil 5 mg/ml (1 ml diluted in 10 ml saline) was given intra-arterially, particularly when tibial angioplasty was performed.

By the end of the procedure, completion angiogram was performed to determine technical success. Technical success was defined as continuous patency of the treated artery without any obvious flow-limiting lesions.

Patients were examined postprocedurally for retrieved pulse to determine clinical success. This was defined as retrieval of foot pulses (dorsalis pedis/posterior tibial pulses) or clinical improvement (good capillary circulation, warmth, relief of rest pain and good healing of ulcer or minor amputation).

Patients were followed up for a period of 6 months. Patients were evaluated as regards patency rates and limb salvage. Only patients with disappearance of peripheral pulse were subjected to duplex examination.

### **Definitions**

**Hypertension** was defined by medication requirement to maintain a systolic blood pressure less than 140 mm Hg.

**Cardiac disease** was defined as a history of angina pectoris, myocardial infarction, congestive heart disease, or prior coronary artery revascularizations (Bakken et al, 2007)

**Chronic renal impairment** was defined as a serum creatinine level of 1.5 mg/dl in a patient on permanent dialysis.

**Cerebrovascular disease** included a history of stroke, transient ischemic attack, or previous carotid artery revascularization.

**Minor tissue loss:** nonhealing ulcer, focal gangrene with diffuse pedal ischemia. (Rutherford et al, 1997)

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**Major tissue loss:** extending above Tarsal Metatarsal level (Rutherford et al,1997)

**TASC II** was used to categorize femoropopliteal lesions, **TASC I** was used to categorize infrapopliteal lesions.

**Runoff vessel** was defined as a patent, crural vessel continuing from the popliteal segment.

**Technical success** was defined as continuous patency of the treated artery without any obvious flow-limiting lesions (Chisci et al, 2012)

**Limb salvage:** in patients complaining of rest pain and without foot ulcers, the disappearance of pain with discontinuation of analgesic therapy was considered as successful limb salvage. In patients with foot lesions, limb salvage was considered successful if plantar standing was maintained, even when achieved by a tarsal-metatarsal amputation. (Chisci et al, 2012) (Faglia et al, 2006)

**Failure:** In patients in whom treatment did not relieve rest pain or the gangrene extended above the ankle joint, a major amputation (above-the ankle) was proposed and performed. Any major amputation was considered as a failure. (Faglia et al, 2006). Also, procedure related complications necessitating urgent surgical intervention were considered a failure of endovascular management.

**Major amputation** was defined as loss of a sufficiently functional foot remnant (to allow standing and walking) and necessitating the fitting of a prosthesis, i.e. above and below knee amputations. (Faglia et al, 2012)

**Minor amputation** constituted ray and fore-foot amputations. (Faglia et al, 2012)

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P value<0.05 was set as the threshold of statistical significance (Rabellino et al, 2010)