

EVALUATION AND MANAGEMENT OF PERIPHERAL ARTERIAL DISEASE IN TYPE 2 DIABETES MELLITUS

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ABSTRACT

The aim of present study was to a) assess the type and the distribution of peripheral arterial disease in diabetic patients presenting to the Endocrine Clinic. b) Plan revascularization and limb salvage of the affected limbs. During the past one year we evaluated and managed eleven patients of type 2 Diabetes and limb-threatening lower extremity ischemia from the moment of diagnosis to revascularization and limb salvage. These patients presented with predominant ischemic symptoms and signs. The patients were subjected to a complete clinical evaluation, recording of the Ankle Brachial Index, Color Doppler Scan and Digital Subtraction Angiography (DSA) of the lower limbs. Depending on the type of the lesion surgery or angioplasty procedures was performed.

We had eleven patients who had presented with an ischemic limb. The mean age of the patients was 60.4 ± 5.2 years and duration of diabetes was 12.4 ± 4.1 years. The presentation was ischemic ulcer on the great toe in 2/11 (22.2%), gangrene 2/11 (11.1%) one of them had bilateral gangrene, claudication and rest pain in 7/11 (44.4%). The peripheral pulses dorsalis pedis and posterior tibial was absent or feeble in 10/11 (90.9%), femoral artery pulses were feeble in 54.5% (6/11). The ankle brachial index was 0.55 ± 0.24 . The findings on the Duplex ultrasound scan and DSA were comparable. DSA had an additional advantage of demonstrating the arterial vascular anatomy of the lower limb. The lesions seen were (i) Non visualization of small arteries dorsalis pedis and posterior tibial in 3/11 (27.3%). Aortic disease was present in 3/11 (27.3%). Ilio-Femoral lesion in 36.4% (4/11) and Popliteal artery aneurysm 9.1% (1/11). . Surgery with vascular graft was done in 36.4% (4/11) and angioplasty and stent placement in 18.2% (2/11). There was a significant improvement post procedure. Amputation was done in 27.3% (3/11). The patient with bilateral gangrene underwent bilateral below knee amputation

The patients who present with features of peripheral vascular disease should undergo recording of ankle brachial index, Duplex ultrasonography and angiography. They should be offered limb salvage revascularization procedure.

KEY WORDS: Peripheral arterial disease; Diabetes mellitus. Percutaneous transluminal angioplasty.

INTRODUCTION

Peripheral arterial disease is observed more frequently in patients of diabetes as compared with age-matched controls. With ultrasound Doppler assessment peripheral artery disease is found in 30% of all diabetic patients and occurs ten years earlier. (1). Lower limb atherosclerosis in the diabetic patient is characterized by preferential involvement of the lower leg, *e.g.*, in 70% of diabetic patients compared with only 20% of non diabetic patients. Involvement of the deep femoral artery is also typical of diabetes. Other abnormality that is seen with diabetes is stenosis of multiple arterial segments. The risk factors predisposing to macroangiopathy and ischemic foot lesions are the same as the risk factors in non-diabetic patients, particularly smoking. The diabetic patient is also at an excess risk for due to constellation of risk factors especially uncontrolled hyperglycemia (2).

It is now possible for patients with lower limb ischemia to get a precise assessment of the peripheral arterial disease with preoperative imaging of the peripheral vessels. Intra arterial digital subtraction angiography (DSA) has been considered the gold standard in diagnostic imaging for the evaluation of peripheral arteries (3). A significant number of advances have been made in the recent past in the revascularization techniques for peripheral arterial disease (PAD). Percutaneous transluminal angioplasty and vascular surgery are now established treatment of PAD (4). We present our experience of peripheral arterial disease in patients of type 2 diabetes.

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PATIENTS AND METHODS

During the period Jan 2002 to Sep 2002 we evaluated and managed eleven patients of type 2 Diabetes with Fontaine Grade II to Grade IV limb-threatening lower extremity ischemia as per the Trans Atlantic Guidelines on evaluation Peripheral Arterial Disease (4). The evaluation procedure consisted of the following

History and Physical Examination

Patients were evaluated by the Rose Questionnaire for intermittent claudication (5). Claudication was defined as pain or discomfort in the calf of either leg that was not present at rest and began with walking exercise. The peripheral arterial pulses of DP (dorsalis pedis), PT (posterior tibial) and FA (femoral artery) pulse of each foot was recorded as normal (distinct) and considered abnormal if either diminished or feeble (attenuated but palpable) or absent. Other findings of chronic limb ischemia such as trophic changes, changes in the color of the skin and muscle wasting were also recorded. The patients were also evaluated for any systemic disease such as hypertension, coronary artery disease and any other illness.

Calculation of Ankle Brachial Index (ABI)

The ankle brachial index was evaluated in the supine position, after a 5-minute rest. A cuff was placed on each arm and ankle, and a Doppler ultrasonic instrument (model 801, Parks Electronics) was used to detect each pulse. The cuff was inflated to 10 mm Hg above systolic pressure and deflated at 2 mm Hg/sec. The first reappearance of the pulse was taken as the systolic pressure. The systolic pressure was taken a second time, and the two values were averaged. If any pair of values differed by more than 6 mm Hg, repeat pressures were taken, and the average of the most consistent pair was used for subsequent analysis. Pressures were obtained in the following order: right arm, right DP, right PT, left DP, left PT, and then left arm. Once the four ABI values were obtained (right and left DP and PT ratios), a value of ABI of less than 0.9 was considered significant (6). These patients were subjected for further studies.

Color Doppler Sonography

The Color Doppler examination was done by an experienced Vascular Radiologist. The procedure of the examination was to trace the vascular pulsation from the abdominal aorta to bifurcation

of the abdominal aorta. Arterial tree from common iliac, femoral, popliteal, posterior tibial and dorsalis pedis artery were mapped. The blood flow, arterial diameter and velocity were recorded in each artery. A diseased segment was identified as the artery with poor blood flow, decrease in amplitude and velocity of the blood flow or absence of blood flow.

Digital Subtraction Angiography (DSA)

All DSA procedures were performed by experienced angiographers with a Poly star Top unit (Siemens Medical Systems, Erlangen, Germany). The procedure consisted of retrograde puncture of the ipsilateral common femoral artery with a 20-gauge puncture needle that was connected with a slim tube and multiple manual injections of contrast material. Three of 11 patients underwent selective DSA with crossover antegrade catheterization of the common femoral or superficial femoral artery using a 5-French side-hole catheter. The number of projections that were performed was at the discretion of the angiographer. For visualization of the complete arterial tree, an average of 90-110 ml of a nonionic contrast agent was used. For selective injections into the arteries of one leg, 40-60 ml of contrast medium was sufficient. No vasodilatory drugs were administered during the DSA procedure.

PTA Procedure

PTA was performed according to the technique of Grüntzig and Hopff (7). During each catheter intervention, 5000 IU unfractionated heparin was given intra-arterially as thrombosis prophylaxis. After PTA, acetylsalicylic acid, 100 mg/D and Clopidogrel 75 mg/day, was given as standard treatment.

Vascular Graft Surgery

The vascular surgery was performed by an experienced vascular surgeon. Under general anesthesia the diseased arterial segment was identified and a arterial graft was placed in-situ. 5000 IU unfractionated heparin was given intra-arterially as thrombosis prophylaxis

RESULTS

We had eleven patients who had presented at Endocrinology Clinic with an ischemic limb. The details are in Table 1. The mean age of the patients was 60.3 ± 5.4 years with male to female distribution of 9:2. The mean duration of diabetes

was 12.4±4.1 years. There was a high prevalence of hypertension, and other co morbidities. Coronary artery disease was present in 45.5% these patients. More than half of the males were smokers or ex smokers.

Table 1-Characterstics of the Patients (n=11)

Characteristic	Mean ± SD
Age (years)	60.4 ± 5.2
Sex (Male:Female)	9:2
Duration of Diabetes (years)	12.4 ± 4.1
Smoker/Ex-smoker	63.3% (7/11)
Hypertension	72.3% (8/11)
Coronary Artery Disease	45.5% (5/11)

The presentation was ischemic ulcer on the great toe in 2/11 (18.2%) of the patients, both lower limb gangrene 1/11 (9.1%), claudication and rest pain in 7/11 (63.6%) and claudication and digital gangrene in 1/9 (9.1%). The peripheral dorsalis pedis and posterior tibial was absent in 6/11 (54.5%) and feeble in 3/11(27.3%). The ankle brachial index was 0.55±0.24 (Table 2). The findings on the Color Doppler ultrasound scan and DSA were comparable. DSA was also helpful in demonstrating the vascular anatomy of the lower limb. The lesions seen were: non visualization of small arteries dorsalis pedis and posterior tibial. These patients had presented with an ischemic ulcer of the toe. Bilateral distal popliteal block was observed in the patient with gangrene of both the limbs. Aortic disease was present in two patients. One of these patients had an almost complete block before the bifurcation. Iliofemoral lesion were seen 4/11 (36.4%) of the patients and the lesions were complete common iliac block, internal iliac narrowing and femoral narrowing. Popliteal artery aneurysm was seen in one patient.

Table 2: Vascular Abnormalities in Patients

Abnormality	% of Patients
Mean ankle Brachial index (ABI)	0.55 ± 0.24
<i>Peripheral Pulses (Absent or Feeble)</i>	
Dorsalis Pedis & Post Tibial	90.9% (10/11)
Popliteal Artery	63.6% (7/11)
Femoral Artery	54.5% (6/11)
<i>Doppler Ultrasound & DSA</i>	
<i>Localization of lesion</i>	
Aortic Disease	27.3% (3/11)
Iliofemoral disease	36.4% (4/11)
Popliteal artery	9.1% (1/11)
Non visualization of Dorsalis Pedis and Post Tibial	27.3% (3/11)

Out of the eleven patients the 3/11 (27.3%) patients with small artery disease were managed conservatively (Table 3). The management was daily dressing, antibiotics to control the infection and hyperbaric oxygen therapy. Angioplasty was done in two patients with iliofemoral disease. On angiography, these two patients had stenosis which were <50% of the vessel diameter. The disease segment was <10 cm in length. Patients with stenoses >50%, diseased arterial segment longer than 10 cm and/or multiple/calcified underwent vascular surgery with a vascular graft placement. In 4/11 (36.3%) patients the vascular surgery was done. The patients were evaluated post procedure and there was a significant improvement post procedure as demonstrated by ABI and Colour Doppler. Flow and waveform improved significantly after PTA and vascular surgery. Clinical recurrence occurred in one patient after surgery and this patient had a graft thrombosis and gangrene and had to undergo a below knee amputation subsequently. Three patients had to undergo an amputation. The patient with bilateral gangrene had a bilateral below knee amputation and the other patient had a digital disarticulation. One patient had a post surgical amputation.

Table 3: Intervention and Outcome

Intervention and Outcome	No. of Patients
Conservative Management (Dressing, antibiotics 7 hyperbaric oxygen therapy)	27.3% (3/11)
Angioplasty (Iliac & femoral artery)	18.2% (2/11)
Arterial Graft (Aortic disease and iliac arterial graft 36.3% (4/11)	
Amputation (Below knee, digital disarticulation)	27.3%(3/11)

DISCUSSION

As the population of most developing nations grows, atherosclerosis has becoming a major health problem. Although the focus of research has concentrated on the coronary and cerebral forms of the disease, peripheral arterial disease has received little attention either from epidemiologists or clinicians. The prevalence of peripheral arterial disease (PAD) differs according to age, sex, and geographical location varies between 0.4 and 14.4% based on the symptoms of intermittent claudication, diagnosed by the Rose questionnaire (6). A similar variability

from 4.2 to 35% is seen when the disease is diagnosed by the ankle brachial pressure index (9). The reported prevalence of PAD in Indian population based on ABI is 3.5% (10).

The diagnosis of peripheral arterial disease is based on the symptom of intermittent claudication. The "Rose questionnaire" has been used extensively to quantify the claudication (6). The diagnosis requires to be confirmed by the non-invasive primary imaging modalities. A commonly used noninvasive test for PAD is the measurement of systolic blood pressures in the ankles and arms with a Doppler ultrasonic instrument, from which the ankle/brachial index (ABI) is derived (11). A low ABI is highly predictive of the presence of arterial occlusive disease. Most of the studies take a cut of 0.9 for significant arterial disease. It has been suggested that a resting ABI of 0.9 is up to 95% sensitive in detecting angiogram-positive disease and almost 100% specific in identifying apparently healthy individuals (12).

An abnormal ABI should be followed by duplex ultrasound Color Doppler Sonography (CDS). The Color Doppler Sonography is a good non-invasive method of delineating the peripheral arteries. The findings of CDS can be compared with an intra arterial digital subtraction angiography in the evaluation of the peripheral arteries in patients with peripheral arterial occlusive disease (13,14). Magnetic resonance angiography holds out promise for the future as being a good method of non-invasive imaging (15). We evaluated all the patients who had symptoms of PAD and low ABI initially by the CDS and followed with digital subtraction angiography.

In general, surgery or angioplasty is indicated to relieve disabling symptoms when medical therapy had failed for treatment of limb-threatening ischemia, symptoms of rest pain, ischemic ulceration and gangrene. Surgery or angioplasty is also indicated for bypassing the sources of thrombo-embolism. With the recent developments it is now possible to intervene in PAD and salvage the limb. The modalities are percutaneous transluminal angioplasty (PTA) and vascular surgery. The selection of patients for surgical bypass, endarterectomy and or angioplasty is guided principally by the severity clinical symptoms and type of lesion on DSA. The discrete, proximal, short-segmental lesions are the most amenable to surgical intervention (16). We could offer PTA in two patients with demonstrable lesion in femoral and external iliac artery. Angioplasty has become an established therapy for

PAD. This modality is accepted not only in the larger arteries but also in disease of the infrapopliteal artery. In a recent published study PTA was performed in 85.3% of the patients. There was a significant improvement of ABI and tissues oxygen concentration after PTA. Only 5.2% underwent an above-the-ankle amputation. The conclusion of the study was that PTA is feasible in most diabetic subjects with ischemic foot ulcer and is effective for foot revascularization. Clinical recurrences are infrequent. In subjects treated successfully with PTA the above-the-ankle amputation rate was low. PTA should be considered as the revascularization treatment for all diabetic subjects with foot ulcer and PAD.

When the lesion are not technically feasible for angioplasty such as a block greater than 10 cm, concentric lesion or lesion in aorta or common iliac artery; such lesions are best subjected to vascular surgery. The surgery is excision of the diseased segment and graft replacement. We performed surgery in four patients. Three of these patients had a successful revascularization and only one patient had graft thrombosis. There has been demonstrable improvement after surgery as shown by postoperative Color Doppler blood flow and the post operative ABI. Similar results have been demonstrated in a series of 55 patients undergoing vascular arterial bypass graft surgery for lower limb peripheral arterial disease. Post surgery there was improvement in transcutaneous oxygen tension of the revascularized extremity. Not only did the surgery improve the vascularity of the lower limb but also retarded the progress of the neuropathy (17).

In conclusion peripheral arterial disease is common in diabetic population. With the present day investigative modalities it is possible to detect the exact site and type of lesion affecting the peripheral arteries. The patients should be offered intervention in the form of angioplasty or vascular bypass surgery. Not only we can save the limb but improve the function of the limb.

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