ROLE OF ENDOVASCULAR REVASCULARIZATION PROCEDURES IN CHRONIC LIMB ISCHEMIA INVOLVING SUPERFICIAL FEMORAL ARTERY

Amol Rathod, Vivek Ukirde*, Saurabh Joshi, Ashank Bansal, Arvind Borde, Akshay Gursale, Sagar Satpute, Rajiv Hira

ARTICLE INFO

Keywords: PVD, SFA, Atherectomy, DCB, Stenting

ABSTRACT

Peripheral vascular disease (PVD) of the lower extremity is an important cause of morbidity and affects 10 million people in India, most of the time it involves superficial femoral artery. Various endovascular procedure can be used to treat peripheral arterial diseases. We are presenting case series of 35 patients which are presented with complains of peripheral vascular disease were treated with various combination of endovascular procedures like angioplasty, atherectomy and stenting. At 1 and 6 months follow up, all patient show significant clinical improvement.

1. Introduction

Peripheral vascular disease (PVD) of the lower extremity is an important cause of morbidity and affects 10 million people in India, usually presented in younger to older age group (mean age group- 45) in Indian with risk factor like diabetes and smoking and various other factors. Atherosclerosis of the major vessels supplying the lower extremities, causing stenosis and occlusion of arteries, hence patient complain of muscle pain on walking (intermittent claudication). The claudication impairs walking distance and reduces quality of life. Critical limb ischaemia is the most severe manifestation of the disease can lead to limb loss.

PVD is caused by various risk factors. Sedentary life style, high cholesterol diet, diabetes and smokers are at particularly high risk of developing critical limb ischaemia. Various treatment options include conservative management with lifestyle modification, medications, endovascular management of plain balloon angioplasty, drug coated balloon angioplasty, stenting and atherectomy. Surgical management in the form of bypass grafts. Surgical bypass was considered the "gold standard" for treatment of peripheral arterial disease since a long time. However, endovascular management with percutaneous transluminal angioplasty with or without stenting with addition of atherectomy is becoming a primary treatment option of lower extremity peripheral arterial disease recently.

Current care includes lifestyle modification (exercise and smoking cessation), medical therapy (antiplatelet agents such as aspirin or clopidogrel, cilostazol, lipid-lowering drugs, and adequate blood pressure control), and revascularization (surgical or endovascular). The appropriate treatment option is decided based on the clinical staging & accompanying co morbid conditions. Inspite of all these modalities the 1-year limb loss reported in these cases is 20%.

This article describes our experience of various endovascular revascularization methods such as atherectomy, angioplasty with or without stenting in treatment of chronic limb ischaemia of lower extremity mainly involving superficial femoral artery (SFA).

AIMS & OBJECTIVES: 1. To evaluate efficacy of various endovascular revascularization procedures (atherectomy, angioplasty with or without stenting) in CLI involving SFA.

2. To evaluate efficacy of the treatment at 1 and 6 months interval.

Inclusion Criteria: Patients presenting with clinical symptoms of CLI, Rutherford grade I- VI with diseased SFA. In other word symptomatic patients of chronic lower limb ischaemia involving superficial femoral artery (SFA) disease diagnosed on - Doppler ultrasound, CT angiography, Digital subtraction angiography (DSA).

Exclusion Criteria: Patients not consenting for the study pregnancy, Patients with known h/o contrast allergy. High risk patients having multiple co-morbidities.

* Corresponding Author : Dr. Vivek Ukirde
Email: druvrays@hotmail.com

Copyright 2010 BioMedSciDirect Publications IJBMR - ISSN: 0976-6685. All rights reserved.
**Materials and Methods:**

Informed written consent obtained. Patient conformed to inclusion & exclusion criteria as described above. A brief history was taken from each patient regarding symptomatology and duration of disease. A focused clinical examination with the aid of the referring physician was undertaken as regards to severity and extent of involvement of the disease.

A detailed clinical and laboratory evaluation was done for all patients. Data regarding age, sex, diabetes, hypertension, hyperlipidaemia, smoking, tobacco intake, renal insufficiency was collected. Bilateral lower limb CT angiography and doppler scan to look for flow in distal ATA & PTA. Pre procedure ABI was obtained. All the patients were evaluated and grouped according to Rutherford grading based on symptoms and TASC II classification based on imaging. Based on clinical examination, colour doppler & CT angiographic images treatment plan was decided to used POBA, atherectomy or stenting. Informed consent was obtained from the patients. Ethical clearance from Institutional Review Board (IRB) was obtained.

**Patient Cohort:** From Feb 2018 to August 2019, 35 patients were taken, 30 were male and 5 are female. 2 or more of risk factors (hypertension, diabetes, and smoking) were present in all patients. Most of the patient belong to age group 50-59 (mean age – 58.6 year). 4 patients were less than 50 yrs. of age.

Clinically, all are grouped according to Rutherford classification from III to VI (category III-213, IV-17, V-3, VI-2). According to TASC- II, 13 patients were categorized in TASC B, 11 in category C and D each. The mean pre-operative ABI was 0.62 in our study.

Out of 35 patients, atherectomy was performed on 7, angioplasty on 10, both atherectomy with angioplasty on 13 patients and stenting was performed on 5 with atherectomy and angioplasty.

**Procedure:**

Following protocol was followed with all aseptic precautions and local anaesthesia.

Femoral access was taken and 7 or 8 Fr sheath. Angiograms were taken in more than one projection to know current status of the vessel. Hydrophilic guide wire 0.035” wire (Terumo), 0.014” wire (Nitrex- Medtronic, Command-Abbott) was used for crossing the occlusion.

In case of Atherectomy - Directional Atherectomy device (TurboHawk™, Covidien, Plymouth, Medtronic) was then used over 0.014” guide wire. Atherectomy was performed in the occluded areas by using multiple passes along different directions. Post- Atherectomy angiogram was taken, followed by drug coated balloon angioplasty (DCB). Multiple chunks of calcified plaques were excised in all patients using the device.

In percutaneous transluminal angioplasty (PTA) was done using plain balloons (POBA) or drug eluting balloon (DEB) so called drug eluting balloon angioplasty (DEBA). Most of the time drug used for coating is paclitaxel, few of the cases serolimus coated balloons were used.

The size of the balloon is selected based on the diameter of the parent vessel, length of occluded segment.

Balloons were inflated at 8 to 12 atmospheres, and inflation was maintained for 2-3 min. In case of suboptimal angiographic results, repeated inflations were performed.

In case of suboptimal plasty showing residual stenosis of more than 30% post plasty, recoiling of the occluded segment post plasty & dissection, decision of stenting was taken. In all the cases of stenting, vasculomimetic stent (supera- Abbott) was deployed. For SFA diseaselistent (Bard) may be used.

Technical success was considered if residual stenosis is less than 30%. All patients received systemic anti-coagulation in form of subcutaneous heparin (Inj. Clexane, 0.6mg B.D.) for 3 days and anti-platelet therapy (Aspirin-150mg, Clopitab -75mg) lifelong. Patients were evaluated on follow-up at 3 day, 1 and 6 months for symptomatic relief, limb salvage and ABI.

**RESULTS:**

Patient were followed at post-operative day 3, 1 month and 6 months. During follow up examination, patient was evaluated clinically, ABI and doppler. At the end of 6-month majority of the patients show clinical improvement. All patients show compliance to drug and lifestyle modifications.

On post-operative day 3 all patients showed good flow across the treated segment with good flow velocity distal to it on doppler examination.

At the end of 6 months, mean improvement in ABI is seen maximum in case of patient who were treated with both atherectomy and angioplasty (0.82±0.13) followed by angioplasty only (0.80±0.14), stenting (0.78±0.16) and atherectomy (0.75±0.18). (Fig 1)

Also, maximum improvement is seen the patient treated with combination of POBA and DEB (0.85±0.05) as compared to only POBA (0.72±0.22). (Fig 1)

**Figure 1:** showing Line diagram depicting trend of improvement in mean ABI after revascularization procedure.

**Figure 2:** shows Stacked bar diagram by clinical follow up according to Rutherford classification.
DISCUSSION:

The prevalence of peripheral vascular disease (PVD) of the lower extremity is increasing in the Indian population due to various risk factors like diabetes, smoking and hypertension. It is more common in male patients as reflected in our study, there were more number of male patients (n=30) as compared to female patients (n=5) with male to female ratio of 6. The range of age varied from 20 years to 80 years (mean age 60.63 years) with peak incidence between 50-59 years. Incidentally left limb was (66%) found to be more affected than right limb (34%). Various risk factors are involved in the development of peripheral vascular disease like diabetes, hypertension, smoking, tobacco intake, etc. Out of these smokers being the most common (65.72%) followed by diabetes (57.14%) and hypertension (54.28%).

Patient were presented with range of symptom. Among this claudication being the most common, rest pain with tissue loss being second common and worrisome presentations. These patients were referred by clinician in view of absent peripheral pulse, to evaluate the arterial system.

After patient history & clinical assessment, these patients were further categorised clinically according Rutherford and Fontaine classification. All patients undergo radiological evaluation through different modalities such as lower limb doppler, CT angiography and DSA. ABI was also calculated; average ABI was 0.62 found in our study. On the basis of imaging patients were further categorised with TASC II classifications.

Out of 35 patients 7 were subjected to atherectomy, 10 patients for angioplasty, 13 patients had undergone both atherectomy with angioplasty, 5 patients were treated with SFA stenting. All the patients for stenting were preceded by atherectomy & angioplasty. Post procedural assessment was done with USG doppler at the end of 1 month and 6 months. Technically successful revascularization is noted in all the treated patients. All patients (35) showed immediate successful recanalization of SFA.

Patient were followed up clinically according Rutherford classification into R1 to R6. Pre-operative distribution of R3, R4, R5 and R6 grades is 37%, 48%, 9% and 6% respectively. There were no patient belongs to R1 and R2 group. (Fig. 2.)

Significant change in the Rutherford grading is noted at end of 1 months. There is significant downgrading in Rutherford grading noted.

Out of 35 patients treated, 85% patients were in the R3 & R4 of clinical grading. At the end of 6 months the number of patients reduced to 35% in R3 & R4. Remaining 50% patients of R3 & R4 clinical grading initially were shifted to R1 & R2 of clinical grading showing effectiveness of endovascular treatment. (Fig. 2.)

Atherectomy removes the plaques from the arteries, it also offers various other advantages such as lack of barotrauma, resulting in reduced risk of neointimal hyperplasia and dissection. The rates of failure / restenosis are significantly lower with adjuvant drug coated balloons. (6)

Native artery is left as it is, which is better future intervention if needed. Various atherectomy devices including directional atherectomy devices like the SilverHawk and TurboHawk Atherectomy devices, orbital atherectomy devices, rotational atherectomy device, the 5R rotablator device are available. The SilverHawk and TurboHawk plaque excision systems are US Food and Drug Administration-approved directional atherectomy devices. The TurboHawk Atherectomy Catheter has an over the wire design using 0.014-inch guidewire.

Angioplasty disrupts the atherosclerotic plaque by displacing it radially. This action results in stretching of the adventitia thereby in creasing the lumen diameter of the treated vessel. Currently, the most commonly utilized endovascular revascularization options are percutaneous transluminal angioplasty (PTA) with provisional stenting or primary stenting. Provisional or selective stenting is indicated for the treatment of flow limiting dissections and/or persistent, hemodynamically significant stenoses or recoils after PTA. This approach is recommended by the Tran-Atlantic inter-Society Consensus document II (TASC II) when treating SFA disease. However, both PTA alone and primary stenting can successfully treat SFA disease. (7)

PTA has the advantage of being inexpensive and technically simpler than primary stenting, PTA alone avoids using foreign bodies that may be a potential stimulus for intimal hyperplasia. The Stent fatigue and fracture may result from the torque and deformation of the femoropopliteal arteries that occurs during flexion of the knee joint. Further, the advent of lower profile angioplasty balloons allows PTA of the SFA through vascular sheaths as small as 5 French. Smaller sheath diameters result in fewer complications, and therefore, are considered safer. In addition, the ease of re-intervention or bypass of an angioplasties arterial segment following PTA may be advantageous. The presence of a stent may impede endovascular re-intervention if a re-stenosis result in occlusion of the stented arterial segment. Moreover, angioplasty preserves collateral vessels that may be compromised by stent placement.

The disadvantage of our study, however is the limited follow-up of 6 months of our patients. Various randomized controlled trials with atherectomy device have shown a higher restenosis rate at follow up.

CONCLUSION:

Endovascular revascularization procure is an useful treatment for lower limb atherosclerotic arterial disease. Combination of Atherectomy and angioplasty (POBA and DEB) offers significant clinical improvement. The cost and availability are some of the practical issues limiting its use. Also, long term follow up data is needed for better outcome.

References:


