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Original Article

Atherectomy in treatment of lower extremity peripheral arterial disease

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ABSTRACT

Peripheral vascular disease of the lower extremity is an important cause of morbidity and affects 10 million people in India1. Atherectomy is an useful adjunct in already established endovascular techniques for lower limb atherosclerotic disease. We present a case series of 15 patients who presented with complains of peripheral vascular disease and were treated using atherectomy device. At one and six month follow up, all the patients showed significant clinical improvement. The cost and availability are some of the practical issues however limiting its use.

1. Introduction

Peripheral vascular disease (PVD) of the lower extremity is an important cause of morbidity and affects 10 million people in India. Unique features of PVD in Indians is presentation at younger age (mean age 45 years) and increased association with diabetes. Prevalence of PVD is now growing in India due to advancing age of general population and increased incidence of diabetes1.

Treatment of peripheral atherosclerotic disease in the lower extremities is quite challenging. Various treatment options include conservative management with lifestyle modification and medications, endovascular management consisting of balloon angioplasty using drug coated or non-drug coated balloons, stenting and atherectomy and 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 is becoming a primary treatment option of lower extremity peripheral arterial disease recently. A new addition to this is the removal of the arterial plaques with the help of atherectomy devices2.

A “non-interventional” management is the first choice for patients with intermittent claudication: smoking cessation, nutritional counselling, exercise program, strict control of diabetes and hypertension and medication (antiplatelet agent and statins)3,4.

Removing of atherosclerotic plaque offers the advantages such as elimination of stretch on arterial walls, less rates of restenosis, avoiding permanent placement of foreign body such as stent intraluminally with its corresponding complications and keeping all further options open in cases of recurrence.

This article describes our experience of atherectomy devices in treatment of atherosclerotic plaques of lower extremity.

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AIMS & OBJECTIVES

1. To evaluate efficacy of atherectomy device in lower limb arterial disease.

2. To evaluate these patients on follow up at 1 and 6 months

MATERIALS & METHODS

We present a case series of 15 patients who presented with complains of lower limb peripheral arterial disease. A detailed clinical and laboratory evaluation was done for all patients. Data regarding age, sex, diabetes, hypertension, hyperlipidemia, smoking, tobacco intake, renal insufficiency was collected. Bilateral lower limb CT angiography and doppler scan to look for flow in distal ATA & PTA and to calculate ABI was done. All the patients were evaluated and grouped according to Rutherford and TASC II classification systems. After evaluation of angiographic images, decision was taken to use atherectomy devices. Informed consent was obtained from the patients and ethical clearance from Institutional Review Board (IRB) was obtained.

Patient Cohort: Of the 15 patients, 12 were male and 3 were female. 2 or more of risk factors (hypertension, diabetes, smoking and hyperlipidemia) were present in all patients. Clinically, all patients fell in Rutherford III to VI category (category III-3, IV-4, V-6, VI-2). 7 patients were categorized in TASC D, 4 in category C, 1 in category 1 and 3 in TASC A. 13 patients had ABI between 0.2 to 0.6, 2 patients had ABI beyond 1.2, secondary to heavily calcified vessels.

Procedure: Femoral access was taken and 7 or 8 Fr sheath introduced in all patients. The occlusion was crossed using hydrophilic 0.035”wire (Terumo) in 13 patients and using 0.014” wire in 2 patients (Nitrex, Medtronic).. The 0.035” wire was exchanged with 0.014” wire and Directional Atherectomy device (TurboHawk ™, Covidien, Plymouth, Medtronic) was then used. Atherectomy was performed in the occluded areas by using multiple passes along different directions. A distal embolic protection device was not used. Post-Atherectomy angiogram was taken, followed by drug coated balloon angioplasty (DCB) (Medtronic) (Image 1,2,3,4). No complication due to atherectomy device was noted in any of the 15 patients. Multiple chunks of calcified plaques were excised in all patients using the device (image5,6). Co-existing iliac disease noted in 2 patients, and was

treated using angioplasty and stenting. Technical success was considered if residual stenosis was 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 1, 3 and 6 months for symptomatic relief, limb salvage and using ABI.

RESULTS

Patients were evaluated at 1 month and 6 months. During follow up examinations, patients were evaluated clinically, on Doppler and for ABI. At one and six month follow up, all the patients showed significant clinical improvement. Lifestyle modifications and drug compliance was good in all the patients as per patient feedback.

On doppler, the treated vessels showed did not show any occlusion with good velocity flow in the vessel as well as distal to it. Increase in ABI was noted in all the 13 patients with ABI between 0.2 to 0.6. 7 patients in Rutherford category III and IV, experienced relief in symptoms (resolution of rest pain or improvement in claudication distance). In the 6 patients, presenting with gangrene, level of amputation was confined to digits. Satisfactory wound healing was noted in all the 8 patients in Rutherford category V and VI (Image 7). 1 patient with rest-pain had persistence of symptoms, despite persistently improved ABI and no residual stenosis on follow-up angiogram.

DISCUSSION

Peripheral vascular disease (PVD) of the lower extremity is becoming increasingly common with increasing prevalence of diabetes, smoking and hypertension in the Indian population.

In endovascular management, atherectomy is an useful adjunct. Atherectomy removes the plaques from the arteries rather than compressing them against the arterial wall as is the case with angioplasty and stenting. It also offers various other advantages such as lack of barotrauma, resulting in reduced risk of neointimal hyperplasia and dissection. Secondly, with adjuvant drug coated balloons, the rates of failure / restenosis are significantly lower. With atherectomy, native artery is left as it is, leading to better chances of reintervening, if needed in the future5.

Various atherectomy devices including directional atherectomy devices like the SilverHawk and TurboHawk Atherectomy devices, orbital atherectomy devices, rotational atherectomy device, the Rotablator device are available5.

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. The device consists of two disposable parts, the catheter and the battery-driven motor that powers the cutting blade (Image 8). The distal end of the catheter consists of a rotating cutting blade and a nosecone, distal to the cutting blade, with a reservoir for collecting the plaque as it is removed. When the motor is turned on, the reservoir is opened, the cutting blade exposed, and the window in the tip of the catheter containing the cutting blade is deflected toward the vessel wall to engage the cutting blade against the plaque6.

With the blade spinning at 8000 rpm, the catheter is slowly and smoothly advanced across the lesion, shaving the plaque from the vessel wall. When performing atherectomy, it is recommended that the device be advanced slowly and methodically to reduce the risk of distal embolization. After two to six passes, depending on the length of the lesion, the device must be removed and cleaned: the atheroma must be removed from the nosecone. Once cleaned, the device may be reinserted and atherectomy continued. Also ensure adequate anticoagulation (ACT, activated clotting times of 275 to 300 seconds) to avoid thrombotic complications during the procedure5,6.

The risks associated with atherectomy include dissection, perforation or rupture of the arteries, arterial spasm, arterio-venous (AV) fistula, embolism in distal arteries5,6. As with any device requiring mechanical deployment and retraction, there exists a risk of mechanical failure of the device resulting in potential surgical intervention.

One of the major concern with atherectomy devices is distal embolization by fragments of plaques, as the devices cut plaques physically7,8. We in our study didn't use the atherectomy device due to technical and cost issues, however post procedure angiograms didn't reveal evidence of embolism in any of the 15 patients.

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 after 2 years9,10.

CONCLUSION

Atherectomy is an useful addition in endovascular treatment of lower limb atherosclerotic arterial disease. Combination of Atherectomy and DCB 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 to compare its results with primary stenting and / or balloon plasty and vascular surgery.

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