Original Article

Overcoming Difficult Chronic Total Occlusion: Increasing the Applicability of Endovascular Intervention to Patients with Challenging Re-entry: Double Balloon Technique in Crossing Challenging Chronic Total Occlusions

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Abstract

Context: Chronic total occlusions (CTOs) sometimes are a challenge for endovascular intervention, especially in developing countries where new devices used to cross CTOs are either unavailable or too expensive. Using basic endovascular tools remains the only solution in such cases when patients were at high risk for open surgical intervention. We present our experience of using double balloon technique to cross CTO lesions in the femoropopliteal segment after failure of known traditional techniques, i.e., intraluminal, subintimal angioplasty, and subintimal arterial flossing with antegrade–retrograde intervention (SAFARI technique). We looked for technical success of double balloon technique in such difficult CTO.

Aims: To assess the safety and applicability of double balloon technique in crossing long and complex CTOs lesions, where new crossing re-entry devices are unavailable.

Subjects and Methods: This is a retrospective study to look into cases between November 2013 and October 2015, in Kasr Ani Hospital, Cairo University, Egypt.

Results: The success rate of the technique was 100%.

Conventional Methods: Intraluminal, subintimal angioplasty, and SAFARI technique for crossing CTOs in the femoropopliteal territory were used in 350 lesions, but it failed in 30 where double balloon technique was used. The technical success rate of the technique was 100%.

Conclusions: Double balloon technique was safe and cheap. It should replace the use of new re-entry devices keeping them only in bail-out cases after the failure of this technique.

Key Words: Challenging chronic total occlusion lesions, critical limb ischemia, double balloon technique, endovascular intervention

Introduction

Endovascular interventions have become preferred alternative to surgical intervention even in long, complex lesions affecting femoropopliteal territory.1-3

Crossing the calcified femoropopliteal chronic total occlusions (CTOs) are the most technically challenging and are prone to complicate. Successful endovascular revascularization depends on how these lesions are crossed and are re-entered in the distal patent artery.4 The femoropopliteal vessel is a muscular vessel with thick tunica media with atherosclerotic plaques continues over a long segment, and they are thick and calcified.5 Critical limb ischemia is the most severe clinical manifestation of peripheral arterial disease, and it carries major morbidity and mortality in those who usually have relatively shorter life expectancy.6,7 Traditional techniques for CTO recanalization; intraluminal and subintimal angioplasty carry a failure of 25%.8 Many advanced techniques and new tools have been developed to improve CTO recanalization. Most of these clinical techniques and tools aim to make subintimal channel across CTO cap facilitating getting re-entry to true lumen.9 Successful re-entry of CTO lesions needs the operator to be patient and skillful (familiar) in different maneuvers for CTO recanalization; subintimal recanalization of Bolia, subintimal arterial flossing with antegrade–retrograde intervention (SAFARI), and available new re-entry catheters. New re-entry devices are expensive and unavailable in many developing countries putting interventionist in a real critical situation. Since double balloon technique has been described two decades ago, it

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has not been widely applied on challenging femoropopliteal CTO lesions. Double balloon technique may offer a solution for these challenging lesions and the need for new expensive re-entry catheters may be abounded.

**Subjects and Methods**

**Interventions**

This is a retrospective study done between November 2013 and October 2015. These were 350 patients; 250 (71.5%) males and 100 (28.5%) females. Their ages ranged from 45 to 72 with mean age 58.3 ± 10.26. Patients were classified for CLI as per Rutherford classification, and they were considered for intervention if the patient classified as Rutherford class IV, V, or VI.

All patients underwent complete physical examination and preoperative assessment for the preprocedural risk factors; coronary heart disease, hypertension, stroke, renal impairment, and diabetes. Cardiologist was consulted to evaluate the patient cardiac condition and risk for surgical intervention.

The lesions were classified according to TASC II classification after it were examined by both duplex ultrasound and computed tomography angiography of the aorta and both lower limbs.

All patients were informed of the risks and benefits of the procedure and signed institutional informed consent before the procedure.

**Access; antegrade, ipsilateral common femoral artery (6 F) or contralateral femoral puncture (8 F Sheath AVANTI™, Cordis, a Johnson and Johnson).**

Angiographic runs were obtained with sufficient overlap to cover the whole limb.

**Crossing chronic total occlusion lesion and angioplasty**

**Conventional methods for crossing chronic total occlusion**

Intraluminal crossing of lesion; in which angled hydrophilic glide wire (Terumo, Boston Scientific/Vascular) advanced to the level of occlusion under angiographic guidance and once the level of occlusion 4 F vertebral catheter was used to keep wire in central position.

Subintimal angioplasty was attempted by keeping the angled tip of the wire directed to the wall, then advancing wire in the subintimal plane. Short angled tip of 4 F vertebral catheter was used to redirect re-entry. Re-entry position confirmed by injecting small amount of dye.

**Advanced techniques**

Retrograde access of popliteal or pedal vessels was obtained if antegrade attempt of crossing CTO was unsuccessful. Choice of distal access depended on the extent of the lesion and fitness of the patient; popliteal access was not preferred in the obese patient. Local anesthetic infiltration was not used in cases of pedal access to decrease external compression. After the access had been gained mixture of 100 mcg of glyceryl trinitrates and 5000 IU of heparin (70–80 IU/kg) was given.

Using road map techniques or reference picture with same degree of intensifier, the tip of the needle headed directly to the desired artery and needle should be parallel to the beam with brief fluoroscopy to align the needle and minimize radiation hazards. After the access had been gained mixture of 100 mcg of glyceryl trinitrates and 5000 IU of heparin (70–80 IU/kg) was given.

**Figure 1:** Roadmap technique in inserting distal access; the right one: Needle headed the popliteal artery, the left: angiography did after the popliteal sheath inserted.
a wire of the distal access. The two balloons abutted each other with 1 mm in between, and then both wires were pulled back in the shaft to be just below the balloon. Both balloons were inflated simultaneously. Distal guidewire was manipulated into antegrade sheath or catheter creating flossing type guide wire access. If the wire failed to do so, the two balloons were inflated while the tips of each balloon overlapped the other balloon. That maneuver was repeated several times until the intervening plaque was crushed and distal wire created a flossing guide wire. The length of overlapped segment was changed with each inflation [Figure 2 and Video 1].

If continuous subintimal channel was not obtained another modification was attempted; low profile 4 F vertebral catheter extended over the retrograde wire. The sharp end of the wire just protruded from the tip of the catheter. Both the catheter and the wire were pushed gently while they were rotated. At several attempts of these trials, the distal wire created a continuous subintimal channel. The wire of the distal access removed keeping the vertebral catheter in place. A small amount of the dye was injected to confirm the formation of the new subintimal channel. The distal guide wire was reinserted with its floppy soft end in advance to get out the antegrade access completing the procedure from the antegrade access [Figure 3 and Video 2].

All patients underwent PTA of the target lesions. Appropriate balloon sizes were determined on the basis of the diameter of the reference vessel adjacent to each lesion. The choice of specific balloon catheters and inflation times and pressures were left to the discretion of the investigators according to the target lesion.

Follow-up and postprocedure medications

Nearly, all patients are initiated and maintained on antiplatelet therapy with aspirin 325 mg (once daily) and clopidogrel 75 mg (once daily) to reduce platelet adhesion and activation. This aggressive antiplatelet approach is maintained for 4–6 weeks following completion of the procedure.

Results

Over a period of 20 months; a total number of 350 patients, 250 (71.5%) males and 100 (28.5%) females, ages ranged from 45 to 72 with a mean age of 58.3 ± 10.26, underwent recanalization of CTO lesions in their femoropopliteal vessels.

Preprocedural comorbidities were found to be as shown in Figure 4. All patients were presenting with critical limb ischemia [Figure 5]. Anatomic characteristic of the lesions of lower limb ischemic [Figures 6 and 7].

Complex lesions were 22.86% of which 37.5% double balloon technique used [Figure 8]. All lesions in which double balloon used had successfully vascularized with no complication related to this techniques.

About 22.85% of all cases underwent a secondary bailout stenting procedure because of an inadequate PTA result, either a flow-limiting dissection (17.1%) or a residual stenosis 5.7%, after multiple balloon inflations. The mean stent length was 80.63 ± 27.05 mm.

Discussion

SFA is commonly affected in atherosclerotic chronic lower limb ischemia. The atherosclerotic plaque of SFA tends to be continuous over the long segment, diffuse, and total occlusion. Endovascular intervention has many advantages over surgical management in whom medical treatment fail, it offers rapid convalescence less morbidity; (exposure to anesthesia and wound infection) and preserving the chance of future open vascular intervention if these techniques failed. The
The main goal of successful endovascular procedure is how to successfully cross CTO lesion which may be challenging and time-consuming. It is preferable to cross CTO lesions intraluminal, but the wire tends to get through the subintimal plane; the proximal cap of CTO lesions is thick, fibrotic. The distant re-entry of the wire is where the plaque taper, this may jeopardize important collaterals and worsen the degree of limb ischemia. New re-entry devices are expensive, and they are not available all time.

Retrograde CTO recanalization improves the high failure rate; 20–40% of standard antegrade recanalization techniques of the endovascular intervention. Inserting popliteal access while the patients in the supine position decreases patient discomfort extending the application of the retrograde approach to large scale of patients in whom retrograde recanalization was contraindicated. Double balloon technique extends endovascular intervention after failure of SAFARI technique in the management of CTO lesions. Most of the published studies using double balloon technique in BTK angioplasty as there were no specific safe re-entry devices available. In our cases, inflation of kissing balloons or overlapped balloon several times with changing the length of overlap in each time fritted the atherosclerotic plaque in-between. Inflation of overlapped balloons was gradual and at low pressure and limited to pain to avoid complication; vessel rupture. In our technique, the double balloons inflated while they were partially overlapped which is not published in the literature for tibial recanalization. SFA atherosclerotic plaque is thick fibrotic, and the diameter of the SFA can accommodate inflation of two small balloons (3 mm and 4 or even 5 mm) to nominal or just below nominal pressure. These multiple inflations fritting the plaque in between.

In 7% of these challenge cases, atherosclerotic plaque failed to be crossed in spite of these fritting forces applied to it. Sharp recanalization by the advancement of the stiff end of the wire supported by low profile vertebral catheter through the crushed plaque aided the creation of continuous subintimal channel. Sharp canalization technique also has been published in few series. It has a good penetration power with incidence of subsequent vessel perforation. This technique used very cautiously, very gentle after the plaque had weakened by the fritting effect of the double balloon technique and the sharp end of the wire replaced by its floppy soft end as soon as the subintimal channel created.

**Conclusions**

Double balloon technique is safe, simple technique extending endovascular intervention application. It should
be used as a second step ladder for CTO recanalization of the SFA lesions after the failure of SAFARI technique. Re-entry devices should be kept after the failure of double balloon technique. Sharp recanalization by the stiff end of the wire may aid the double balloon technique in creating continuous subintimal channel in difficult cases with less incidence of complication.

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**Conflicts of interest**
There are no conflicts of interest.

**References**
1. Norgren L, Hiatt WR, Dormandy JA, Neilson MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007;45 Suppl S: S5-S67.
2. Hong MS, Beck AW, Nelson PR. Emerging national trends in the management and outcomes of lower extremity peripheral arterial disease. Ann Vasc Surg 2011;25:44-54.
3. Dosluoglu HH, Lall P, Cherr GS, Harris LM, Dryjski ML. Superior limb salvage with endovascular therapy in octogenarians with critical limb ischemia. J Vasc Surg 2009;50:305-15, 316.e1-2.
4. Schmidt A, Bausback Y, Piorkowski M, Werner M, Bräunlich S, Ulrich M, *et al.* Retrograde recanalization technique for use after failed antegrade angioplasty in chronic femoral artery occlusions. J Endovasc Ther 2012;19:23-9.
5. Whyman MR, Ruckley CV, Fowkes FG. A prospective study of the natural history of femoropopliteal artery stenosis using duplex ultrasound. Eur J Vasc Surg 1993;7:444-7.
6. Hua WR, Yi MQ, Min TL, Feng SN, Xuan LZ, Xing J. Popliteal versus tibial retrograde access for subintimal arterial flossing with antegrade-retrograde intervention (SAFARI) technique. Eur J Vasc Endovasc Surg 2013;46:249-54.
7. Green JS, Newland C, Fishwick G. Positive outcome following unsuccessful subintimal angioplasty. Eur J Vasc Endovasc Surg 1998;16:266-70.
8. Montero-Baker M. The retrograde approach for BTK chronic total occlusions. Tools and techniques for achieving access in even the most complex cases. Endovascular Today 2014;5:55-64.
9. Fanelli F, Lucatelli P, Allegretti M, Corona M, Rossi P, Passariello R. Retrograde popliteal access in the supine patient for recanalization of the superficial femoral artery: Initial results. J Endovasc Ther 2011;18:503-9.
10. Rogers RK, Dattilo PB, Garcia JA, Tsai T, Casserly IP. Retrograde approach to recanalization of complex tibial disease. Catheter Cardiovasc Interv 2011;77:915-25.
11. Chang JC, Lin LS, Chiu CH. Static contrast technique for creating transpedal arterial access in patients with tibioperoneal occlusions. J Vasc Surg 2013;58:1120-2.
12. Chin H’ng MW, Punamiya S. An innovative modification of the retrograde approach to angioplasty and recanalization of the superficial femoral artery. Diagn Interv Radiol 2014;20:164-7.
13. Mohler E 3rd, Giri J; ACC; AHA. Management of peripheral arterial disease patients: Comparing the ACC/AHA and TASC-II guidelines. Curr Med Res Opin 2008;24:2509-22.
14. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JE, *et al.* Bypass versus angioplasty in severe ischaemia of the leg (BASIL): Multicentre, randomised controlled trial. Lancet 2005;366:1925-34.
15. Botti CF, Ansel GM. Creative access techniques for CTOs new technology and unconventional approaches help to maximize success in difficult cases. Endovascular Today 2006;3:85-8.
16. Akkus NI, Beedupalli J, Varma J. Retroperitoneal hematoma: An unexpected complication during intervention on an occluded superficial femoral artery via a retrograde popliteal artery approach. Rev Port Cardiol 2013;32:623-7.
17. Adams GL, Gardner SJ. Exotic access, techniques, and devices for infrapopliteal CTOs: Recommendations on how to successfully cross chronic total occlusions of the infrapopliteal vasculature. Endovascular Today 2012;5:44-9.
18. Huang HL, Chou HH, Wu TY. Endovascular sharp recanalization for calcified femoropopliteal artery occlusion. Case Rep Cardiol 2012;2012:510627.
19. Slonim SM, Nyman U, Sembø CP, Miller DC, Mitchell RS, Dale MD. Aortic dissection: Percutaneous management of ischemic complications with endovascular stents and balloon fenestration. J Vasc Surg 1996;23:241-51.
20. Ingle H, Nasim A, Bolia A, Fishwick G, Naylor R, Bell PR, *et al.* Subintimal angioplasty of isolated infragenicular vessels in lower limb ischemia: Long-term results. J Endovasc Ther 2002;9:411-6.