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OUTBACK catheter for treatment of superficial femoral and iliac artery chronic total occlusion: Experience from two centers

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Abstract

Purpose: The OUTBACK® catheter is a reentry device that enables reentry into a vessel lumen from the subintimal space during subintimal angioplasty. It is reserved for cases where reentry has not been possible using conventional wire and catheter techniques. We report a two-center experience in recanalization of the chronic total occlusions of the common iliac (CIA) and the superficial femoral artery (SFA) using the OUTBACK® catheter in cases where other techniques were unsuccessful. **Material and Methods:** All cases where recanalization was performed using the OUTBACK® reentry catheter between January 2010 to January 2015 were retrospectively identified and included in this study. 21 patients were identified. The indication for intervention in these cases included claudication and critical leg ischemia. In all cases, conventional recanalization could not be successfully achieved. **Results:** The OUTBACK® catheter was used to recanalize 10 SFA occlusion and 9 CIA occlusions. In 19 patients (90%), reentry into true arterial lumen was successfully achieved. 17 patients had their recanalization through the transfemoral approach whereas 2 patients had a transpopliteal artery approach. In 2 patients, reentry into the true lumen could not be achieved using the OUTBACK® catheter due to patient's intolerability for the procedure and severe atherosclerotic calcified plaques. There was 100% patency of the vessel intervened on Duplex ultrasound at 24 months of follow up. 16 patients (84%) remained asymptomatic and 2 patients (10.5%) reported worsening of their symptoms due to the development of new lesions within the arterial system. **Conclusion:** The OUTBACK® catheter is an effective and safe technique for reentry into the vessel lumen when conventional techniques fail.

Key words: Chronic total occlusion; common iliac artery, OUTBACK® catheter; reentry device; superficial femoral artery

Introduction

Chronic total occlusion (CTO) can be present in up to 40% of symptomatic peripheral vascular disease patients and is defined as a lesion that has been present for more than 3 month and exhibits Thrombolysis in Myocardial Infarction (TIMI) flow grade 0 or 1.[1,2] Percutaneous recanalization

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of the CTO of iliac and superficial femoral artery (SFA) segment can be a technically challenging procedure with a reported failure rate of 25%,[3] and therefore, after a failed intraluminal attempt, most operators proceed to a subintimal approach accessing the subintimal space at the site of the occlusion. The intraluminal reentry can pose a major challenge, and failure to achieve this may result in the distal extension of the dissection, creation of arteriovenous fistula, and occlusion of the distal collaterals. To overcome the problem of reentry, certain devices have been designed such as fluoroscopically guided OUTBACK® Ltd Reentry Catheter (Cordis, USA), reentry balloons, and Intra-Vascular Ultra Sound (IVUS) guided Pioneer Plus Catheter PPLus120 (Medtronic, USA).

We conducted an audit of patients who were treated with OUTBACK® catheter for CTO of the iliac and SFA in two different interventional radiology centrer. All of these patients were clinically followed up for an average of 24 months with Doppler ultrasound to ascertain the patency of the target vessel.

Materials and Methods

The OUTBACK® catheter, introduced in 2005, has a hollow 22G needle to be advanced through a side port at the tip for luminal reentry under fluoroscopic guidance [Figure 1]. 5000 IU of intraarterial heparin was administered at the start of all the procedures. Vascular access was gained by either the Seldinger's technique or by ultrasound-guided single-wall puncture of the common femoral artery (CFA) or the popliteal artery (PA), followed by placement of a 6Fr sheath (Cordis, USA). Once the proximal end of the occlusion of the SFA and distal end of the iliac artery occlusion was reached, an intentional subintimal access was achieved by the established technique[4] using either a hydrophilic angled 0.035 wire (Terumo, Japan) or a 0.018 wire (Advantage Terumo, Japan). A 4Fr multipurpose catheter (Cordis, USA) was used as a support catheter. When the estimated distal end of the occlusion was reached subintimally, a 0.014 wire was exchanged over which the OUTBACK® catheter was advanced to the distal end of the occlusion, and two orthogonal angiographic views were taken. The OUTBACK® catheter was advanced on a 0.014 wire. The orientation of the tip towards the intraluminal reentry site was established utilising the T and L-shaped fluoroscopic marker. After withdrawing the 0.014 wire back into the OUTBACK catheter, the 22G nitinol curved needle component was fired through the sideport from the distal segment of the device into the vessel lumen.[5] The 0.014 wire was advanced into the true lumen of the vessel followed by withdrawal of the OUTBACK® catheter once position of the wire within the lumen was confirmed. A low profile balloon used over the 0.014 wire and a low profile balloon angioplasty of the reentry port was performed to facilitate the subsequent 0.035 wire exchange and definitive angioplasty balloon manipulation. This was followed by angioplasty and/or stenting using self-expanding stents.

Figure 1: OUTBACK® catheter with a deployed curved 22G nitinol needle

Retrospective analysis was performed for all recanalizations of the iliac and SFAs where the OUTBACK® catheter was used in two different centers from 2010–2015. In both the units, the OUTBACK® was reserved for cases where there have been failed attempts of intraluminal revascularization. Postprocedural angiograms were reviewed to determine the success of recanalization. Epidemiological details, clinical history, type of lesion (TASC II classification), and indication for intervention was noted.[6] 21 patients were identified. 19 of 21 patients were followed-up for over 24 months after endovascular intervention. The average follow-up period was 24 months (range: 18–30 months).

Technical success was defined as <30% residual stenosis post-angioplasty. Successful reentry was defined as reentry into the true lumen of the nonoccluded artery within 5 cm from the subintimal dissection tract.

Procedural and fluoroscopy times were measured from the first successful arterial puncture to the moment of removal of the sheath.

Results

Summary of results are given in Table 1. 21 patients were identified with age ranging 52–89 years (median 69 years) and a male:female ratio of 2:1. 10 out of 21 (48%) patients had claudication as the main symptom whereas 11 out of 21 (52%) presented with critical leg ischemia with non-healing arterial ulcer in the foot.

7 out of 21 (33%) patients underwent iliac artery recanalization; all of them were performed as a retrograde ipsilateral approach. Of the 14 patients with SFA recanalization, 10 were performed as antegrade ipsilateral approach, 2 with retrograde contralateral approach, and 2 with retrograde popliteal approach.

Successful reentry using OUTBACK® catheter was achieved in 19 out of 21 (90%) cases.

The mean length of the occluded segment in the segment iliac artery was 16.8 cm whereas for the SFA it was 20.3 cm. The average distance between the distal site of the occlusion and the reentry site was 1.8 cm for the iliac artery and 2.8 cm for the SFA. All successful reentry patients were subsequently treated with balloon angioplasty and stent insertions.

The mean procedural time and fluoroscopic time for the iliac artery revascularization was 44.5 ± 6.7 and 31.8 ± 7.4 min, respectively. In the SFA intervention group, it was 59.3 ± 11.5 and 42.7 ± 15.5 min, respectively.

Reentry into the true lumen was not achieved in two cases. In one of these cases, the procedure was abandoned because the patient was restless and was unable to tolerate the procedure. In the other case, the target site of the SFA was severely calcified, limiting the prospects of reentering into the true lumen. Both of these 2 patients eventually underwent elective surgical bypass procedures.

Table 1: Characteristics of the iliac and the superficial femoral artery lesions

Variable	Iliac artery ($n=7$)	SFA ($n=14$)
Age	67.5±5.4 years	71.2±4.7 years
Sex	5 males; 2 females	9 males; 5 females
TASC type lesion	TASC B=1 TASC C=1 TASC D=5	TASC B=2 TASC C=5 TASC D=7
Mean lesion length	16.8 cm	20.3 cm
Mean reentry distance	1.8 cm	2.8 cm
Successful reentry	6/7 (86%)	13/14 (93%)
Stents used	6 (100%)	13 (100%)
Mean procedure time	44.5±6.7 min	59.3±11.5 min
Mean fluoroscopy time	31.8±7.4 min	42.7±15.5 min

TASC: Trans-Atlantic Inter-Society Consensus, SFA: Superficial femoral artery

One patient developed severe flow limiting dissection in the SFA that was treated with low-pressure balloon angioplasty. There were no late complications or death related to the procedures in all 21 patients. All 19 patients (100%) demonstrated patent intervened vessels on follow up Duplex ultrasound scans. 16 patients (84%) remained asymptomatic and 2 patients (10.5%) reported worsening of their symptoms due to the development of new lesions within the arterial system. 1 patient (5%) did not report any improvement of symptoms during the follow-up period.

Discussion

CTOs of the iliac artery and the SFA can be treated either with surgical bypass or endovascular therapy. Surgical bypass is usually performed with saphenous vein harvest or a synthetic graft and carries a higher risk of postoperative complications and longer hospital stay.

Endovascular therapy of these occlusions can be achieved through an intraluminal or subintimal approach. Although intraluminal recanalization of the CTO is optimal, it cannot be always achieved. In these cases, subintimal recanalization is considered to be the primary option where the guidewire dissects into the subintimal space.[4] However, in up to 13–24% of attempted subintimal recanalization procedures, reentry into the true lumen is not possible and can potentially cause significant complications, including compromise of collateral vessels distal to the occlusion and amputation.[7,8] Reentry devices were designed to overcome this challenge and enable a safe and controlled reentry into the true lumen.[9,10]

High cost (approximately $3100) and need for an intravascular ultrasound machine is the major limiting factor to use a Pioneer catheter, even though it provides a direct visualization of the catheter. The Outback® catheter was initially designed for the SFA/PA intraluminal reentry. With time, it was used in the iliac occlusions as well.[11]

There has been a significant improvement in the success rate of reentry into the true lumen using OUTBACK® catheters in treating the lower extremity arteries with recent authors reporting as much as 96% success rate with only 2% periprocedural complication rates.[11,12] Our cases are a mix of iliac and SFA diseases and our true lumen reentry success rate concurs with this study. We have identified the presence of a learning curve for the proficient use of the reentry devices, however, experienced operators who use subintimal techniques regularly excel rapidly.

The majority of superficial femoral angioplasties were performed through an ipsilateral antegrade approach, as long as a disease-free proximal SFA stump was present. In cases where this was not possible, a contralateral retrograde approach was used to deal with the proximal

SFA occlusions, although this possess a major technical challenge and is not recommended or a practical route for OUTBACK® deployment.

In 2 cases of SFA occlusion, the true lumen of the SFA was not cannulated after multiple attempts. In these cases, a transpopliteal retrograde approach was undertaken successfully, the true lumen was cannulated, and occluded segment was treated [Figure 2].

In our two-center experience, we have observed that reentry into the true lumen and subsequent recanalization can be achieved in a majority of the cases. In cases where we failed to reenter the true lumen, it was mainly due to the patient's restlessness and inability to tolerate the procedure. We only administered intravenous analgesics to those patients who were not able to tolerate the procedure. Existing ischemia was further compromised by the additional impedance to the flow due to the presence of catheters and tubes intraluminally. The duration and technical difficulty of the procedure can often make patients restless and aggravate their rest pain.

In our series, we successfully treated two patients with distal aortic and bilateral iliac artery occlusion using OUTBACK® possess a major technical challenge and is femoral artery approach [Figure 3]. In one patient, the initial reentry was made at L2 level, which was above the origin of inferior mesenteric artery (IMA), and therefore a further reentry was made at L3/L4 level. No vascular compromise was noted in the IMA territory on a follow-up contrast enhanced CT scan of the abdomen.

The 3-year stent patency rate in CTO of iliac vessels is 80–90%. These results are comparable with the surgical revascularization using aortobifemoral grafts where the 5-year patency rate has been 88% for critical limb ischemia and 91% for claudication.[13,14] All of our CTO patients who were recanalized using OUTBACK® catheters were treated with bare metal stents. In our experience, the stent patency rate for iliac vessels at 2 years has been 100% following successful recanalization using the OUTBACK® reentry device [Figure 4]. However, this success rate cannot be entirely attributed to the reentry device used for recanalization, and many other factors such as therapies and type of balloon/stents used have to be considered.

The limitation of this study is its retrospective nature with relatively small number of patients. Not all patients had their ankle brachial index readings which could have proven to be more useful and objective parameter for follow-up purposes. The strength of this study is the clinical follow-up for 2 years (except two patients) and the utilization of Duplex ultrasound to document the patency of the vessels.

Our experience shows that OUTBACK® catheter is an effective technique for recanalization of CTOs of superficial femoral and iliac arteries where conventional intraluminal and subintimal approach techniques have failed. It provides

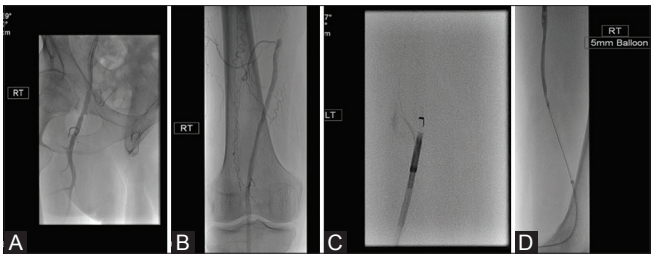

Figure 2 (A-D): Long segment occlusion (A,B) of the superficial femoral artery of a 66-year-old male. Multiple attempts to cross the lesion through antegrade approach failed, and therefore a retrograde popliteal arterial puncture was made. The lesion was crossed subintimally and an OUTBACK® catheter was used to reenter the true lumen (C,D). Subsequently an angioplasty resulted in good angiographic results

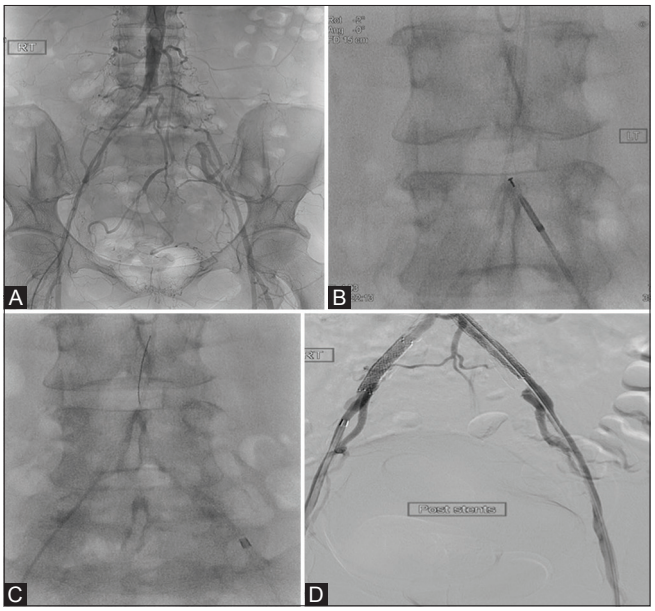

Figure 3 (A-D): Catheter angiogram (A) of a 68-year-old female demonstrating a chronic total occlusion of the left common iliac artery. The occlusion was crossed subintimally and reentry into the distal aorta was made using an OUTBACK® catheter (B,C). This was then treated with angioplasty and stented with good angiographic results (D)

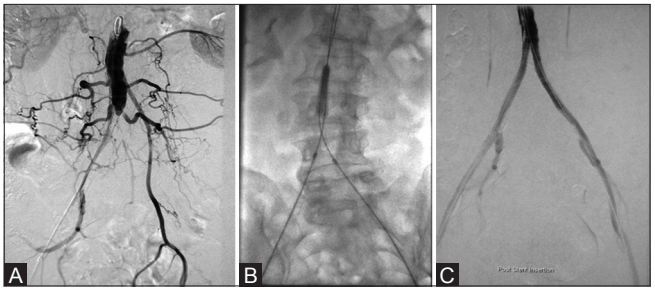

Figure 4 (A-C): Catheter angiogram (A) of a 74-year-old male presenting with severe claudication demonstrating bilateral occluded common iliac artery. Both lesions were crossed subintimally and reentry into the distal aorta was made with OUTBACK® catheter (B). Both lesions were treated with angioplasty and bilateral "kissing stents" were placed with good angiographic results (C)

controlled reentry into the true lumen and has high patency rate at 2-year follow up.

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Conflicts of interest
There are no conflicts of interest.

References

1. Boguszewski A, Torey J, Pai R, Kamalakannan D, Jefic D, Davis T. Intraluminal recanalization of SFA CTOs. Endovasc Today 2010;9:33-8.
2. Surowiec SM, Davies MG, Eberly SW, Rhodes JM, Illig KA, Shortell CK, *et al*. Percutaneous angioplasty and stenting of the superficial femoral artery. J Vasc Surg 2005;41:269-78.
3. Scheinert D, Braunlich S, Scheinert S, Ulrich M, Biamino G, Schmidt A. Initial clinical experience with an IVUS guided transmembrane puncture device to facilitate recanalization of total femoral artery occlusion. EuroIntervention 2005;1:115-9.
4. Bolia A, Miles KA, Brennan J, Bell PR. Percutaneous transluminal angioplasty of occlusions of the femoral and popliteal arteries by subintimal dissection. Cardiovasc Intervent Radiol 1990;13:357-63.
5. Hausegger KA, Georgieva B, Portugaller H, Tauss J, Stark G. The OUTBACK® catheter: A new device for true lumen reentry after dissection during recanalization of arterial occlusions. Cardiovasc Intervent Radiol 2004;27:26-30.
6. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, *et al*. Inter-society consensus for the management of peripheral arterial disease (TASC II). J Vasc Surg 2007;45(Suppl S):S5-67.
7. Lipsitz EC, Ohki T, Veith FJ, Suggs WD, Wain RA, Cynamon J, *et al*. Does subintimal angioplasty have a role in the treatment of severe lower extremity ischemia? J Vasc Surg 2003;37:386-91.
8. Bolia A. Subintimal angioplasty in lower limb ischemia. J Cardiovasc Surg 2005;46:385-94.
9. Gandini R, Fabiano S, Spano S, Volpi T, Morosetti D, Chiaravalloti A, *et al*. Randomized control study of the OUTBACK® LTD reentry catheter versus manual reentry for the treatment of chronic total occlusions in the superficial femoral artery. Catheter Cardiovasc Interv 2013;82:485-92.
10. Smith M, Pappy R, Hennebry TA. Reentry devices in the treatment of peripheral chronic occlusions. Tex Heart Inst J 2011;38:392-7.
11. Ramjas G, Thurley P, Habib S. The use of a reentry catheter in recanalization of chronic inflow occlusions of the common iliac artery. Cardiovasc Intervent Radiol. 2008;31:650-4.
12. Aslam MS, Allaqaband S, Haddadian B, Mori N, Bajwa T, Mewissen M. Subintimal angioplasty with a true reentry device for treatment of chronic occlusion of the arteries of the lower extremity. Catheter Cardiovasc Interv 2013;82:701-6.
13. Leville CD, Kashyap VS, Clair DG, Bena JF, Lyden SP, Greenberg RK, *et al*. Endovascular management of iliac artery occlusions: Extending treatment to TransAtlantic Inter-Society Consensus class C and D patients. J Vasc Surg 2006;43:32-9.
14. Uher P, Nyman U, Lindh M, Lindblad B, Ivancev K. Long-term results of stenting for chronic iliac artery occlusion. J Endovasc Ther 2002;9:67-75.