OUTBACK LTD re-entry catheter in subintimal superficial femoral artery CTO revascularization: Preliminary data about procedure time, radioscopy time and precision in targeting the expected re-entry site compared to manual re-entry technique

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Purpose

To go beyond a chronic obstruction remaining inside the true lumen is extremely difficult, this difficulty being directly proportional to the length of the obstruction itself. In most cases the subintimal way is the sole solution.

Superficial femoral artery chronic total occlusions (CTO) are often challenging for interventional radiologist, being difficult and sometimes impossible to gain a precise in lumen re-entry after subintimal dissection and sometimes requiring a double anterograde femoral and retrograde infrapopliteal approach. This leads to long radioscopy time and raise the risk of complications like the extension of the subintimal dissecation to the true lumen of the patent vessel.

To get out of this problem a specific device has been created, the Cordis® Corporation OUTBACK® LTD® Re-Entry Catheter. It consists of a handle assembly with a rotating hemostasis valve (RHV), a flush port for internal device flushing, a proximal braided shaft for push and 1:1 torque control and a nosecone with 2 directional radiopaque LT marks which permit correct device orientation.

The purpose of this study is to assess the profit and effectiveness of this device to reduce radioscopy and procedure time which are related to a swift and precise re-entry inside the true lumen of the patent vessel.
Methods and Materials

From January 2007 up to March 2007 we performed 52 superficial femoral artery Chronic Total Obstruction revascularization procedures via subintimal approach. The Patients were randomly divided in two groups of 26 units (control group and testing group). Each of them being statistically homogeneous by age, sex, extension and characteristics of the obstructed vessel, stage on Leriche-Fontaine classification for critical limb ischaemia and other clinical settings like diabetes mellitus, hypertension, smoke habit, chronic renal failure.

All Patients have been undergone to double antiaggregant therapy by administration of 100 mg acetylsalicylic acid once a day and 250 mg ticlopidine twice a day starting four days before the procedure and suspending any contingent anticoagulant therapy.

In all cases in which the length of the obstruction was lower than 12 cm (9 cases in the control group and 6 cases in the testing group) we attempted to go beyond it following the true lumen. In no case this attempt has been successful and the procedure have been carried out by subintimal way.

In one group (control group) the first attempt of revascularization has been performed through conventional manual re-entry technique; in the second one (testing group) we performed the revascularization re-entering the true lumen directly with the help of Cordis® Corporation OUTBACK® LTD® Re-Entry Catheter.

Data about total procedure time, radioscopy time and precision in-target re-entry have been collected for all the 52 consecutive patients treated for monolateral SFA total occlusion. In-target re-entry has been defined as a guidewire re-entry into a intraluminal point located within 3 cm after the dissected tract into the patent artery.

The procedure time and radioscopy time were measured starting from the first successful arterial puncture.

The Patients have been followed up to now after the procedure clinically and by Doppler sonography examination to determine the patency of the treated artery at three months interval during the first year and then every six months, thus performing a 36 months total followup.

In all cases informed consent was given.

The first operator was the same for all the Patients.

Procedure time and radioscopy time have been compared using Wilcoxon-Mann-Whitney U test.
In-target successful re-entry rate have been compared using $^2$ test with Yates correction.

**Technique**

Once reached the obstruction of the SFA through an anterograde approach we tried to go directly through it in all the cases it had a length inferior to 12 cm using a 0.035 inches standard straight guidewire carried by a 5F Cook® KMP Catheter. In no case we were able to go beyond the obstruction remaining inside the true lumen. In all that cases in which the obstruction was longer than 12 cm we intentionally gained the subintimal way close to the upstream extremity of the obstruction by pushing the 0.035 inches standard straight guidewire onward the intima. In both cases the shift from the lumen to the subintimal way has been revealed by the winding shape the guidewire showed when pushed forward. Once located subintimally, with the catheter advanced up to the subintimal entry, we changed to a 0.035 inches J-Stiff guidewire and in an alternating manner advanced step by step the guidewire and the 5F Cook® KMP Catheter up to the end of the obstruction.

The steps described above are the same for both groups, the technical essential difference between them being the modality of re-entry inside the true lumen.

In the control group the re-entry into the true lumen have been performed through a series of attempts in which the guide is pushed toward the outer surface of the intima. Because the intima of the patent vessels is often calcified, especially close to the obstruction, this procedure in some cases have led to a prolongation of the dissected subintimal channel far beyond to the obstruction raising the risk of stopping collaterals and prolonging procedure and radioscopy time.

In the testing group the procedure has been performed as follows. Once subintimally reached the downstream extremity of the obstruction we replaced the 0.035 J-Stiff guidewire with a 0.014 wire, removed the catheter and advanced over wire the Cordis® Corporation OUTBACK® LTD® Re-Entry Catheter up to the extremity of the obstruction. At this point the exit port of the device was oriented toward the intimal lumen by visualizing on two orthogonal angiographic views the LT radiopaque markers of the device, then the nitinol cannula was pushed toward the intimal wall, whose crossing is indicated by the free deployment of the 0.014 guidewire. With the guidewire inside the true lumen the device has been retracted and changed with a 3 mm angioplasty balloon to dilate the subintimal channel with its entry and exit sites. In some cases we needed to place stents to maintain vessel patency. We placed self expanding nitinol stents where the artery was non heavily calcified and balloon-mounted stents were it was.
Results

In the control group, where the manual re-entry technique have been used, the procedure has been performed through the traditional anterograde approach in 23/26 (88.4%) cases, in the remaining 3 (11.6%) cases we were obliged to perform the double anterograde femoral/omolateral infrapopliteal retrograde approach that determined by the state of the arteries, which in these three cases were extensively heavily calcified not permitting the single route approach. The in-target re-entry, defined as an in-lumen re-entry within 3 cm from the end of the obstruction, has been accomplished in 11/26 (42.3%) cases. The dissection has been extended beyond this limit in 15/26 (57.7%) cases, but in no case it has been exceeded beyond the popliteal artery. Four (15.4%) stents have been placed in this group. The mean procedure time has been 55.4±14.2 min with a mean radioscopy time 39.6±13.9 min. At the follow-up examinations there have been one case of reocclusion at 6 months, two cases at 9 months and one case at 12 months; in this last case the Patient deceased. Six on 26 (23.1%) Patients were diabetic and 16/26 (61.5%) were smokers.

In the testing group, where we used the Cordis® Corporation OUTBACK® LTD® Re-Entry Catheter, the in-target re-entry has been accomplished in 26/26 cases (100%) with a single intentionally subintimal femoral anterograde approach. Nine (34.6%) stents have been placed in this group. The mean procedure time has been 36.0±9.4 min with a radioscopy time 29.8±8.9 min. At the follow-up examinations there have been one case of reocclusion at 9 months, then this Patient did not sit any more for other examinations, one case at 12 months, also in this case never more sit for other examinations and another case of follow up break off at 18 months, in this last case with no evidence of obstruction at the last exam. Eight on 26 (30.7%) Patients were diabetic and 19/26 (73.1%) were smokers.

All patients were discharged home the day after the procedure without any complications.

Mean procedure time has been 36±9.4 min for the OUTBACK® LTD® assisted re-entry group compared to of manual re-entry group. The procedure time has been 35 % lower using OUTBACK® LTD® catheter than manual re-entry with (p<0.0001).

Mean radioscopy time has been 29.8±8.9 min for the OUTBACK® LTD® group, whilst 39.6±13.9 min for manual re-entry group . The OUTBACK® LTD® group has required a radioscopy time 24.7% lower than manual re-entry group (p<0.001).

The operator using OUTBACK® LTD® catheter have had 100% success rate in in-target re-entry (26/26), whilst using manual re-entry technique it has been only 42,3% (11/26).
In both groups, independently by any previous considered parameter, the re-entry has been successfully accomplished at the popliteal artery.

Four stents were positioned in the first group and 9 stents in the second group.

None intraprocedural major complication related to the procedure has taken place in all patients.
Conclusion

The extreme, and often impossible, difficulty to cross a superficial femoral artery CTO and the high frequency of failure of the balloon angioplasty make these lesions a challenge for the interventional radiologist. With time and experience it was clear that rather than crossing directly through the obstruction it would be feasible to bypass this passing closely to it following the subintimal route. As immediate consequence there was the problem to regain access to the true lumen of the vascularized vessel beyond the obstruction, a maneuver difficult by itself also because of the often calcified intima. Moreover, in that cases in which the intimal re-entry in not achieved immediately close to the end of the obstructed segment there is high risk to exceed, and hence stop, any collaterals.

Among some different techniques to overcome the bulwark represented by the chronic obstruction and re-enter the true lumen, there is the OUTBACK® LTD® re-entry catheter. Other systems are represented by the plain manually guided re-entry technique and the IVUS integrated technique. This last technique is out the scope of this work.

As usual dealing with interventional procedures, the imperatives are technical precision and swiftness. The former to obtain good technical results, the latter to expose the patient as little as possible to ionizing radiations. The plain manually guided technique has been set as the point of reference to assess the added value of the OUTBACK® LTD® technique.

In our experience the re-entry through OUTBACK® LTD® besides being a faster technique is also extremely accurate. In fact the procedure time with OUTBACK® LTD® has been 35% lower than that taken by the plain manual technique with a consequent reduction in radiating time of 24.7%. The accuracy has been absolute in that all the attempts to re-enter the true lumen have been successful (100%) whilst with the manual technique the re-entry has been accomplished in only 42.3% of cases.

No case of any major complication has been happened with both technique used, even though in literature these are shown to be most frequent with the plain manual technique.

The OUTBACK® LTD® re-entry catheter is an accurate and fast tool to regain access into the true lumen of the supplied vessel beyond the superficial femoral CTO segment. Moreover besides warranting successful re-entry in 100% of cases it also permit to spare any collaterals and noticeably reduce the radiating time.

On the base of our experience we strongly recommend to use this tool to obtain a safe and fast access to the supplied vessel beyond the obstruction.
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