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Original Article

Comparison of the OUTBACK® Elite Reentry Catheter and the Bi-directional Approach after Failed Antegrade Approach for Femoro-popliteal Occlusive Disease

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***Aim*: A successful antegrade wire crossing for femoro-popliteal chronic total occlusion (FP-CTO) is still a technical challenge. We attempted to demonstrate the safety and feasibility of the OUTBACK® Elite reentry catheter and the bi-directional approach for failed FP-CTO cases with the antegrade approach.**

***Methods*: Endovascular therapy for FP-CTO was performed in 219 lesions from May 2013 to December 2016 at Morinomiya Hospital. We retrospectively analyzed the data of 43 consecutive lesions which underwent endovascular therapy using the bi-directional approach with distal access and the mono-directional approach with the OUTBACK® Elite reentry catheter for FP-CTO lesions. The antegrade success using a combination of traditional and Intravascular Ultrasound (IVUS) -guided techniques was achieved in 170 lesions out of a total of 219 lesions. From May 2013 to June 2016 (phase 1), the bi-directional approach with distal access was applied to 22 lesions after failed antegrade approaches. From July 2016 to December 2016 (phase 2), the mono-directional approach with the OUTBACK® Elite reentry catheter was applied to 21 lesions.**

***Results*: Clinical and lesion characteristics in phase 1 were not significantly different from those in phase 2. The overall initial technical success rate was 100% in both phases. The total wire number and amount of contrast media were significantly less, and the total procedure time and the total fluoroscopic time were significantly shorter in phase 2 than in phase 1 ($p<0.01$).**

***Conclusions*: Endovascular therapy for FP-CTO using the OUTBACK® Elite reentry catheter is feasible and safe after a failed antegrade approach.**

Key words: Femoro-popliteal cronic total occlusion, Bi-directional approach, OUTBACK® Elite reentry catheter, Failed antegrade approach

Introduction

CTO crossing techniques have recently been developed, including the bi-directional approach technique for femoro-popliteal chronic total occlusion (FP-CTO)[1]. However, a successful antegrade wire crossing for FP-CTO is still a technical challenge.

A typical reason for the antegrade wiring failure is the inability of the guidewire to reenter the true lumen after a subintimal crossing in the occluded segment. The bi-directional approach is effective for achieving a wire recanalization after a failed antegrade approach. However, the bi-directional approach requires many devices and a long procedural time. To cross the guidewire antegradely through FP-CTO with a high success rate, both good skills and specialized devices are required. The OUTBACK® Elite reentry catheter (Cordis, Fremont, CA) is specialized in crossing the guidewire antegradely through FP-CTO after failed antergade approach. This device is widely used to return the wire back into the true lumen and to facilitate a successful endovascular therapy of FP-CTO[2]. In July 2016, the OUTBACK® Elite reentry catheter was authorized in Japan. We describe our experience treating for FP-CTO where the bi-directional approach with distal access and the mono-directional approach

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Table 1. Patients Characteristics

	Phase 1 (Bi-directional, $n=21$)	Phase 2 (OUTBACK, $n=20$)	P value
Age	76.1 ± 8.1	75.5 ± 9.2	0.81
Body mass index	21.3 ± 4.2	22.2 ± 4.3	0.18
Male, %	76.2	70.0	0.62
Claudicant, %	81.0	90.0	0.41
Hypertension, %	81.0	85.0	1.0
Diabetes, %	47.6	40.0	0.76
Dislipidemia, %	47.6	50	1.0
Smoking, %	66.7	50	0.36
Hemodyalisis, %	23.8	15.0	0.70
Anticoagulation therapy, %	23.8	25.0	1.0
Antiplatelet therapy			
Aspirin, %	81.0	80.0	1.0
Clopidogrel, %	61.9	75.0	0.53
Cilostazol, %	52.4	25.0	0.12

Values are presented as mean ± SD or n (%) for categorical variables.

with the OUTBACK® Elite reentry catheter are utilized in order to achieve a successful wire recanalization.

Materials and Methods

Study Population

Endovascular therapy for FP-CTO was performed in 219 lesions from May 2013 to December 2016 at Morinomiya Hospital, Osaka, Japan. We retrospectively analyzed the data of 43 consecutive lesions which underwent endovascular therapy using the bi-directional approach with distal access and mono-directional approach with the OUTBACK® Elite reentry catheter for FP-CTO lesions. From May 2013 to June 2016 (phase 1), the bi-directional approach with distal access was applied to 22 lesions after failed antegrade approaches. From July 2016 to December 2016 (phase 2), the mono-directional approach with the OUTBACK® Elite reentry catheter was applied to 21 lesions. Severely calcified FP-CTO lesions were excluded from this analysis.

None of the patients underwent bypass surgery. Hypertension was defined as systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg, or taking anti-hypertensive agents. Diabetes mellitus was defined as fasting plasma glucose ≥ 126 mg/dl, glycosylated hemoglobin A1C (HbA1C) ≥ 6.5%, or receiving anti-diabetic medications. Dyslipidemia was defined as low-density lipoprotein (LDL) cholesterol ≥ 140 mg/dl, high-density lipoprotein (HDL) cholesterol < 40 mg/dl, or triglyceride ≥ 150 mg/dl. Renal insufficiency was defined as serum creatinine ≥ 1.2 mg/dl. Patients were informed and written consent was obtained. The institutional ethics committee reviewed the protocol and approved this study.

Procedure

After conducting a diagnostic angiography of the lower limbs, we scheduled endovascular therapy for FP-CTO. The endovascular therapy of the FP-CTO lesion was performed with an antegrade approach from the ipsilateral common femoral artery (if proximal of the superficial femoral artery did not have any atherosclerotic lesion) or with an antegrade approach from the contralateral common femoral artery (if proximal of the superficial femoral artery had atherosclerotic lesion) with a 6 French sheath. After sheath insertion, 5000 units of heparin were administered.

Bi-directional Approach Technique

In the phase 1 period, a 0.014 inch stiff type guidewire for the peripheral artery was used to cross the occlusive lesions antegradely with the help of a fluoroscopy, the contrast dye, and Intravascular Ultrasound (IVUS) guidance as previous reported[3].

The bi-directional approach was applied after a failed antegrade approach. A distal access site was chosen from distal superficial femoral artery, popliteal artery, and anterior or posterior tibial artery according to distal run off condition. The 22 G needle was inserted into the distal artery with a fluoroscopically-guided puncture. After a successful puncture, a 0.014 inch guidewire (Cruise; ASAHI INTECC, Japan) was inserted through the needle followed by a micro cath-

Table 2. Lesion Characteristics

	Phase 1 (Bi-directional, $n=22$)	Phase 2 (OUTBACK, $n=21$)	P value
TASC II calcification (n) (A/B/C/D)	0/0/5/17	0/0/5/16	1.0
Occlusion length (cm)	21 [IQR; 20.0-23.8]	21 [IQR; 20.0-24.0]	0.69
Lesion length (cm)	28 [IQR; 25.1-31.5]	28 [IQR; 24.0-32.0]	0.81
Position of distal true lumen (distal SFA/P1/P2/P3)	15/4/1/2	17/2/1/1	0.50
Calcification (n) (none/mild/moderate)	11/5/6	14/3/4	0.53

Values are presented as median [interquartile range], or number.
TASC indicates TransAtlantic Inter-Society Consensus.
IQR, interquartile range.
SFA, superficial femoral artery
P1, from the adductor hiatus to the superior border of the femoral condyle
P2, from the superior border of the femoral condyle to the joint line
P3, from the joint line to the bifurcation of the anterior tibial artery and tibioperoneal trunk

eter without a sheath[1]. The successful bi-directional recanalization approach was mainly achieved by using a rendezvous technique[4].

Hemostasis at the distal access site was achieved with a combination of manual compression and balloon dilatation across the puncture site from within the lumen.

Mono-directional Approach Technique with OUTBACK® Elite Reentry Catheter

In phase 2, a 0.014 inch stiff type guidewire for the peripheral artery was used to cross the CTO lesions antegradely with the help of a fluoroscopy, the contrast dye, and IVUS guidance as previous reported[3]. The OUTBACK® Elite reentry catheter was applied without distal access after a failed antegrade approach. When the guidewire went through subintimal to the distal end of the occlusion, the OUTBACK® Elite reentry catheter was advanced on the wire to the top of the distal true lumen, and two orthogonal angiographic views were taken. The tip was positioned following the T- and L-shaped fluoroscopic marker. After withdrawing the wire back into the OUTBACK® Elite reentry catheter, the cannula stuck into the distal lumen. The 0.014 wire was advanced distally.

Statistical Analysis

Continuous data were expressed as mean ± SD or medians, and categorical data were expressed as numbers with percentages. Continuous variables were compared using either the t-test or Mann−Whitney U test. Categorical variables were compared by the maximum likelihood χ^2 test or Fisher exact test. Two-sided $P<0.05$ was considered to be statistically significant. All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Shimotsuke, Tochigi, Japan), which is a graphical user interface for R (version 2.13.0; The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander (version 1.8-4), designed to add statistical functions frequently used in biostatistics.

Results

Patients' and Lesion Characteristics

There were no differences in any parameter of age, gender, atherosclerotic risk factors, and frequency of anticoagulant and/or antiplatelet agents between the patients in phase 1 and those in phase 2 (**Table 1**).

The lesion characteristics, including the occlusive and lesion length and degree of calcification in phase 1, were not different from those in phase 2 (**Table 2**). In addition, there were no significant differences in position of distal true lumen (distal SFA/P1/P2/P3)[5].

Procedure-related Factors

Antegrade success with combination of traditional and IVUS-guided techniques was achieved in 170 lesions out of a total of 219 lesions. The overall initial technical success rate was 100% in both phases. In all cases in phase 2, the guidewire could reenter the top of the distal true lumen through the cannula of the OUTBACK® Elite reentry catheter without additional access after the subintimal crossing in the occluded segment. All cases in phase 2 could prevent the lesion length extending and losing major collateral. The total procedure time was significantly shorter in phase 2 than that in phase 1 (133 ± 50 vs. 64 ± 21 min, $p<0.01$; **Fig. 1-a**). The total guidewire numbers were significantly less in phase 2 than that in phase 1 (6.0 ± 1.6 vs. 3.0 ± 1.0, $p<0.01$; **Fig. 1-b**).

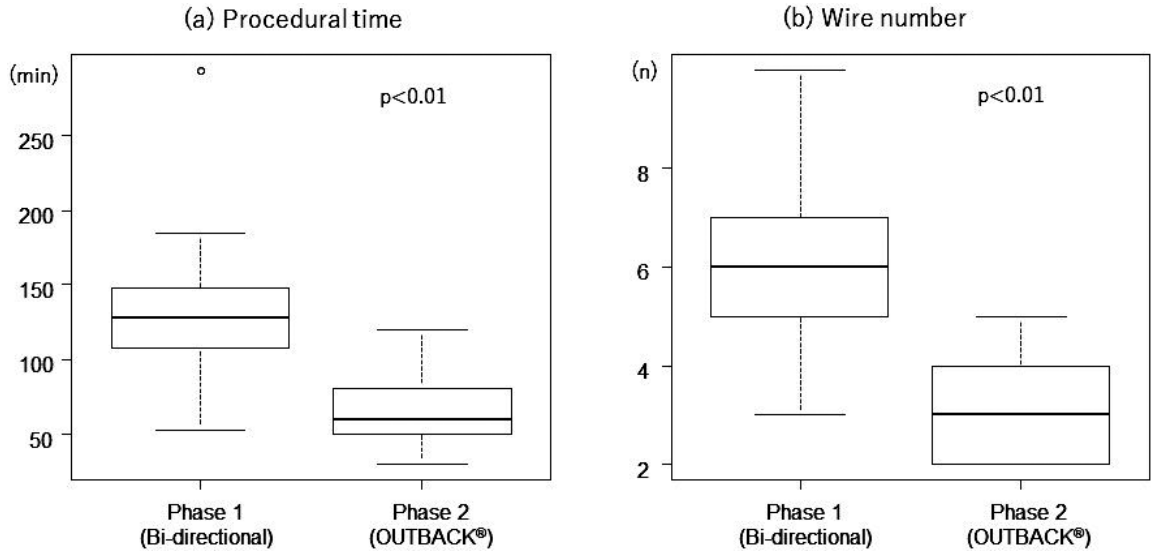

Fig. 1. Comparison of (a) Procedural time and (b) Wire number between Phase 1 and Phase 2.

Contrast Material and Radiation Exposure Time

The total amount of contrast media was significantly less in phase 2 than that in phase 1 (109 ± 67 vs. 75 ± 33, $p < 0.01$; **Fig. 2-a**). The total fluoroscopic time was significantly shorter in phase 2 than that in phase 1 (70 ± 35 vs. 36 ± 17 min, $p < 0.01$; **Fig. 2-b**). On the other hand, there were no differences in the radiation exposure between both phases (310 [IQR; 161-309] vs. 262 mGy [IQR; 126-309]; **Fig. 2-c**).

Cost of Devices Utilized Until the Wire Passage

We calculated the device's cost until the wire passage. The use of all device costs includes puncture needle, sheathe, guide wire, guiding catheter, microcatheter, IVUS, small size balloon, and reentry device usage. There were no significant differences in the device cost until the wire passage between both phases. (414870 [IQR; 317820-464845] vs. 437920 yen (JPY) [IQR; 422920-479620], $p = 0.1685$; **Fig. 3**).

Complications

In phase 1, five cases had arterial spasms and one case had an arterial occlusion at the distal punctured site after hemostasis despite micro catheter cannulation. Two cases took over 30 minutes to complete hemostasis at the distal punctured site. No patients from phase 2 had any complications at the reentry point, such as an arterial perforation or arterial venous fistula. In phase 2, reentry at top of the distal true lumen was achieved in all cases, even though the distal true lumen had a large amount of plaque. Therefore, all cases of phase 2 were treated without extending the lesion length and loosing major collateral.

There was no perioperative complications such as death, major amputation, and reintervention related to the procedures within 30 days in all patients.

Discussion

This is the first study to compare the safety and efficacy of the mono-directional approach by using the OUTBACK® Elite reentry catheter with those of the bi-directional approach. The main findings of this study are summarized as follows: (1) Since approval of the OUTBACK® Elite reentry catheter, antegrade recanalization was obtained in all FP-CTO cases; (2) The total procedural time, the total guidewire number, and the amount of contrast media were more effective with the OUTBACK® Elite reentry catheter than with the bi-directional approach; (3) The OUTBACK® Elite reentry catheter has lower risks of extending the lesion length and loosing collateral by careful manipulation.

Advantages and Disadvantages Regarding Various Wire Crossing Techniques

During the last few years, the advance of techniques and devices has enabled us to try aggressive endovascular therapy for FP-CTO lesions. However, FP-CTO is still one of the most challenging fields due to the particular anatomical morphology of the femoral artery wall that is prone to obstructive disease and high restenosis rate after endovascular therapy[6]. Several reports have suggested that the initial success rate is high but long-term patency is poor in the endovascular therapy of the FP-CTO[7-9]. In order to recanalize

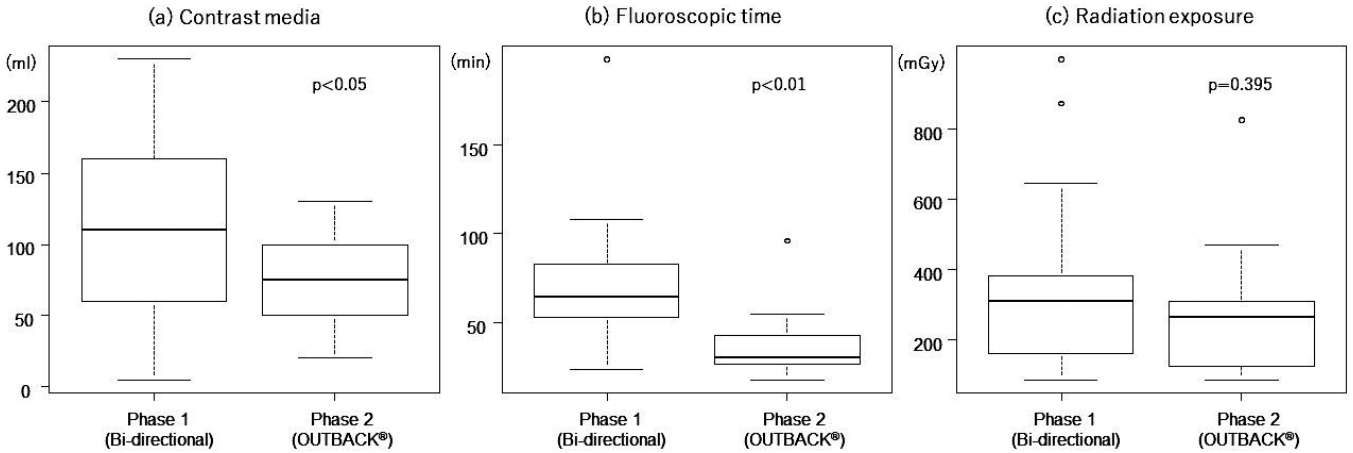

Fig. 2. Comparison of (a) Contrast media, (b) Fluoroscopic time, and (c) Radiation exposure between Phase 1 and Phase 2.

FP-CTO, several techniques, such as the subintimal technique[10], the duplex-guided technique[11], the IVUS-guided technique[3], and the bi-directional rendezvous technique via a various distal artery approach[1, 5], have been developed. A bigger stent area and a higher stent symmetry can be achieved in the intraluminal angioplasty than in the subintimal angioplasty. On the other hand, the intraluminal angioplasty sometimes requires many devices, including a microcatheter and stiff guidewire. More importantly, the total procedural time is longer than that of the subintimal angioplasty, depending on the lesion severity. The bi-directional approach via a distal artery including distal superficial femoral artery, popliteal artery, and anterior or posterior tibial artery has been reported to be a safe and effective method in the treatment of FP-CTO with a high technical success and a reasonable short-term patency rate[1]. However, distal access is sometimes difficult and complicated. General complications of distal access are as follows: arterial spasm and/or occlusion, pseudo aneurysm, artery-venous fistula, insult of nerve, and hematoma. Position change (supine to prone) during the procedure is troublesome and obtaining complete hemostasis is time consuming. On the other hand, in the subintimal technique, a stiff 0.035 inch guidewire is used to dissect the subintimal space, and a stiff-angled catheter passes through the dissected plane to make a reentry in the true lumen. This technique may have its limits because the stiff-angled catheter is unable to reenter into the true lumen beyond the occlusion[12]. In such a case, the OUTBACK® Elite reentry catheter is useful[2]. This device is widely used to get the wire back into the true lumen. To prove clinical feasibility and efficacy of the subintimal angioplasty, Soga *et al.* investigated long-term patency after femoro-popliteal stenting for a long occlusion with the intraluminal and the subintimal approaches. A 3-year patency was similar in both approaches[13]. Based on this result, the subintimal angioplasty is a reasonable approach in technical and clinical terms. The OUTBACK® Elite reentry catheter technique brought us benefits in regard to the decrease of contrast material volume and the short procedural time compared to that of the bi-directional approach. The OUTBACK® Elite reentry catheter techniques are helpful for patients with renal insufficiency and elderly patients who cannot keep a certain position during procedure. Furthermore, carbon dioxide angiography is also useful to save the contrast material volume when adjustment of T- and L-shaped fluoroscopic marker of OUTBACK® Elite reentry catheter[14].

Predictors of Failed Antegrade Approach

In this study, 43 cases out of a total of 219 cases had antegrade failure with regular techniques based on the contrast dye and IVUS guidance. The main reason for antegrade failure was wire performance decrement just before distal true lumen, especially in case of a crossover approach situation. Generally, CTO entrance begins from the bifurcation of superficial and deep femoral artery in most of FP-long CTO. Although ipsilateral antegrade femoral approach is the best way to keep the wire performance, the punctured margin is limited with many cases. Therefore, the crossover approach is one of the predictors of the antegrade failure.

Predictors of OUTBACK® Elite Reentry Catheter Failure

The previous report describes that the reentry success rate with the OUTBACK® Elite reentry catheter was not always successful. Causes of reentry fail-

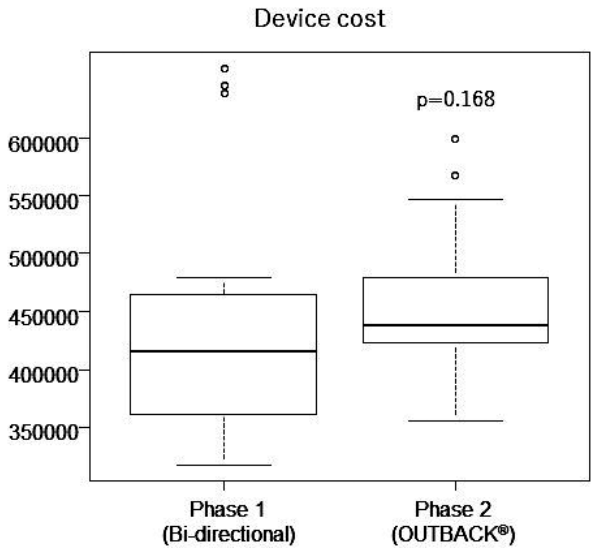

Fig. 3. Comparison of device's cost until the wire passage between Phase 1 and Phase 2.

ure were listed by an inability to reenter the distal true lumen, difficulty tracking the device over a wire, the inability to track over the acute angle of aortic bifurcation, severe calcification at the reentry site, and enlargement by predilatation of the subintimal space[15, 16]. Fortunately, we could obtain successful reentry with the OUTBACK® Elite reentry catheter in all cases. We determined the following factors and procedural steps led to this high reentry rate. 1) We excluded FP-CTO cases with severe calcification; 2) Antegrade wiring never passed over the distal true lumen to avoid enlargement of subintimal space; 3) In order to avoid enlargement of subintimal space, we never dilated the subintimal space with balloon before OUTBACK® Elite reentry catheter was delivered; 4) Reentry site was decided carefully by IVUS information.

Cost of Devices Utilized Until the Wire Passage

Although the total number of guide wires was significantly less in phase 2 than that in phase1 in this study, there were no significant differences in the cost of devices until the wire passage between both phases. This is because the OUTBACK® Elite reentry catheter is 11.7 times more expensive than a 0.014 inch guidewire. The Japanese medical insurance system only reimburses a couple of 0.014 inch wires in each procedure. On the other hand, the OUTBACK® Elite reentry catheter and a couple of 0.014 inch wires are completely reimbursable. The CTO procedure using OUTBACK® Elite reentry catheter is a more cost effective reimbursement for the Japanese system. We did not compare the balloon and stent cost after wire passage between both phase in this study. This is because treatment strategy for FP-CTO is changing from the full-covered stents to the spot-single stent in our hospital.

Study Limitations

Some limitations of this study are noted. First, this study is a non-random, single center study drawn from a relatively small study population. Second, we excluded severely calcified lesions. The subintimal angioplasty for severely calcified lesions cannot achieve enough lumen, and it may lead to poor outcomes. Therefore, the intraluminal angioplasty using various techniques such as the Crosser CTO recanalization system (Bard Peripheral Vascular) should be performed on severely calcified lesions. In addition, the OUTBACK® Elite reentry catheter is not always an effective device for severely calcified lesions due to the kickback phenomenon. Third, in this study, we did not examine the difference between treatment strategies after wire crossing, such as the number of stents and the stent length, because stenting strategies are currently changing. Fourth, we did not evaluate the differences between long term patency in this study. Further studies are required to reconfirm the effectiveness of the bi-directional approach with distal access and the mono-directional approach with the OUTBACK® Elite reentry catheter.

Conclusions

Antegrade recanalization for FP-CTO using the OUTBACK® Elite reentry catheter is feasible and safe when the antegrade wire goes into subintimal space.

Sources of Funding

None.

Conflicts of Interest

The authors declare no conflict of interest.

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