Feasibility of an Intravascular Ultrasound-First Strategy for Below-the-Knee Chronic Total Occlusion Lesions

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Background: Endovascular therapy for below-the-knee chronic total occlusion (BTK CTO) lesions is technically challenging, and retrograde approaches using distal puncture are often required. This study aimed to evaluate the feasibility of an intravascular ultrasound (IVUS)-first strategy in BTK CTO lesions.

Methods: In this single-center retrospective study, 263 patients with chronic limb-threatening ischemia undergoing endovascular therapy for BTK CTO lesions between January 2022 and June 2025 were screened. After excluding stenotic lesions and cases treated with angiography-guided antegrade approach alone, 63 lesions were analyzed. Technical success and procedural complications were evaluated. Among lesions treated with an IVUS-first strategy, a subgroup analysis comparing IVUS-only and crossover cases was performed.

Results: Among 63 lesions, 34 were treated with an IVUS-first strategy, and 29 underwent primary distal puncture. Technical success showed a trend toward improvement in the IVUS-first group (91.2% vs. 72.4%, $p = 0.051$), while complication rates were similar (5.9% vs. 13.8%, $p = 0.29$). In the IVUS-first group, antegrade-only completion was achieved in 70.6% of lesions, whereas 29.4% required crossover to distal puncture. Severe calcification was significantly more frequent in crossover cases (90.0% vs. 29.2%, $p = 0.002$).

Conclusion: An IVUS-first strategy enabled antegrade-only completion in approximately 70% of BTK CTO lesions and may help reduce the need for distal puncture in selected cases.

INTRODUCTION

Endovascular therapy (EVT) for below-the-knee (BTK) arteries is a widespread treatment option for patients with chronic limb-threatening ischemia (CLTI). However, it sometimes can be challenging due to factors such as long chronic total occlusion (CTO), calcification, and small vessel diameter.[1] If the guidewire could not pass through an antegrade approach, we consider a retrograde approach, such as distal puncture. However, retrograde approaches are less practical due to poor distal target vessels.[2] In addition, even if the guidewire passes through, delivery of the balloon or micro catheter may be difficult, making EVT to the BTK artery challenging.

AnteOwl WR (TERUMO, Tokyo, JAPAN) intravascular ultrasound (IVUS)-guided wiring is now used for CTO interventions.[3] This technique makes it easy to perform antegrade wiring because it allows confirmation of the vessel's true lumen and the

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Patient consent statement: For this type of study, consent for publication is not required.

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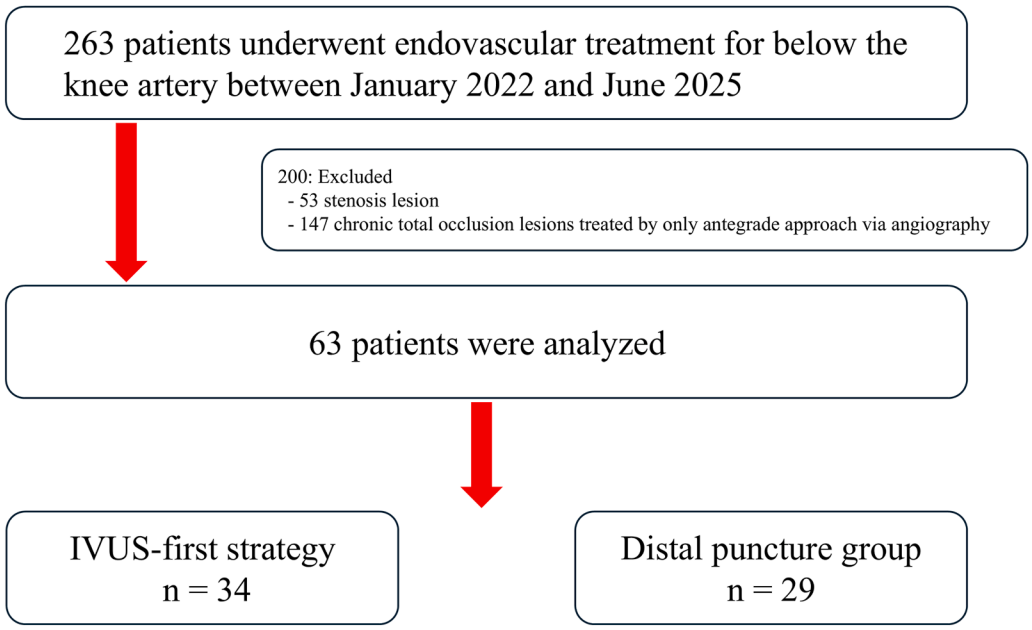

Fig. 1. Study flowchart.

guidewire's direction. The effectiveness of IVUS-guided wiring has been reported in femoropopliteal CTO lesions.[4] In addition, Hayakawa et al. have reported cases in which this technique has been applied to BTK arteries.[5,6] If this technique proves effective, it may be possible to may facilitate antegrade recanalization and reduce the need for distal puncture. This study aimed to determine the feasibility and safety of EVT for BTK CTO lesions treated by IVUS-guided wiring.

METHODS

Study Population and Design

This study was conducted as a single-center, retrospective cohort study. A study flowchart is shown in Figure 1. We enrolled 263 CLTI patients (defined as Rutherford 4–6) undergoing EVT for BTK CTO lesions between January 2022 and June 2025. The exclusion criteria were the presence of stenosis lesions and treatment via only an antegrade approach via angiography. Among the excluded cases, 147 BTK CTO lesions were successfully treated using an angiography-guided antegrade approach alone. Ultimately, 63 lesions were included.

Informed consent was given by all patients for the procedure and subsequent data collection and analysis for research purpose, and the study was approved by the institutional ethics committee.

Procedural Protocol

EVT was performed via an ipsilateral antegrade approach from the common femoral artery using a 5-F or 6-F sheath. Most procedures were performed using a 5-Fr Parent Plus 50 cm sheath (Medikit, Tokyo, Japan). Despite its 5-Fr designation, this sheath has a low-profile design that allows the use of devices compatible with 6-Fr systems, enabling simultaneous use of an IVUS catheter and a secondary guidewire system. This configuration facilitated IVUS-guided parallel wiring without the need for larger sheath sizes. The anticoagulant used was unfractionated heparin. An antegrade approach was performed with a 0.014-inch guidewire with a support catheter. The procedure was performed by passing an intraplaque as far as possible, which was confirmed via angiography. When the guidewire failed to cross the lesion via an antegrade approach, the operator selected either IVUS-guided wiring or a retrograde approach using distal puncture. The choice was primarily based on operator discretion, guided by institutional practice, including subintimal guidewire passage confirmed by angiography and assessment of distal vessel visualization. This reflects real-world decision-making in complex BTK CTO interventions. IVUS-guided wiring was primarily selected when subintimal passage was confirmed, and distal vessel visualization was insufficient for safe retrograde puncture. After crossing the target lesion, predilation was

performed. On the basis of angiographic or IVUS findings, additional balloon dilation was performed with a scoring balloon or high-pressure balloon as needed. The dilation time was decided by the operator but was at least 1 minute in all patients to avoid dissection. All procedures were performed by endovascular specialists with substantial experience in BTK interventions and IVUS-guided techniques. No provisional stenting was performed in BTK lesions in this study, and revascularization was completed using balloon angioplasty alone. The antiplatelet drug administered was aspirin (100 mg/day) with clopidogrel (75 mg/day) and/or cilostazol (100 or 200 mg/day), and its duration was dependent on the patient's background, lesion characteristics, and intervention results. At least one antiplatelet drug was maintained after EVT for all patients.

IVUS Guidance

IVUS-guided wiring was performed according to the EXCAVATOR technique, and AnteOwl WR (TERUMO, Tokyo, Japan) was used in all cases. During this procedure, the guidewire is first advanced as far distally as possible in an antegrade fashion. If the first guidewire is advanced into the subintima, the AnteOwl IVUS is advanced along the first guidewire. In most cases, the first guidewire was positioned in the subintimal space. The IVUS catheter was advanced along this wire to visualize the spatial relationship between the subintimal space and the true lumen. Based on real-time cross-sectional imaging, the second guidewire was carefully directed toward the intraplaque space to achieve re-entry into the true lumen. The second guidewire with a microcatheter is inserted to perform IVUS-guided parallel wiring. The second guidewire is guided to the intraplaque under real-time IVUS guidance. This IVUS-guided parallel wiring allows the passage of all intraluminal guidewires. The IVUS catheter was used solely for visualization and was not advanced as a crossing device. Care was taken to avoid excessive force, particularly in heavily calcified lesions, to prevent device damage.

Study End Points and Definitions

The rates of technical success and complications were analyzed as end points. Procedural complications included flow-limiting dissection, wire perforation, distal embolism, and unusual puncture site bleeding. Wire perforation was defined as contrast extravasation observed during the procedure. Minor perforations without clinical consequence were included, whereas those requiring additional intervention were classified as major complications. Successful EVT was defined as the complete crossing of the lesion by the guidewire and ballooning of the target lesion postprocedure, with <30% residual stenosis. Unsuccessful EVT was defined as a failure to cross the lesion using the guidewire, failure to deliver the balloon to the lesion, absence of flow or slow flow after ballooning, or both.[7]

The J-BTK (Japanese below-the-knee) score was used to assess lesion complexity.[8] This scoring system incorporates factors such as lesion length, calcification severity, and vessel characteristics and categorizes lesions into grades A to D, with higher grades indicating more complex lesions and a lower likelihood of successful guidewire crossing.

Statistical Analysis

Continuous variables are expressed as mean ± standard deviation and were compared using Student's *t*-test for normally distributed data or expressed as median values with interquartile ranges and compared using the Wilcoxon rank-sum test for non-normally distributed data. The Kolmogorov–Smirnov test was used to test the normality of the distribution of all quantitative variables. Categorical variables were presented as frequencies and percentages and compared using the Chi-square test or Fisher's exact test as appropriate. Statistical analysis was performed using JMP (version 18.0, SAS Institute, Cary, North Carolina).

RESULTS

Among 63 lesions, 34 were treated with an IVUS-first strategy, and 29 underwent primary distal puncture. The patients and lesion features are shown in Table I. There were no statistically significant differences in patient characteristics and lesion features between the 2 groups. The proportion of dialysis patients (44.1% vs. 62.1%, $p = 0.16$) and the rate of severe calcification (47.1% vs. 65.5%, $p = 0.14$) were high in both groups, with no significant inter-group differences. There were many challenging cases, with the IVUS-guided group having the higher number of J-BTK grade C cases and the distal puncture group having the higher number of grade B cases. Procedural and intervention results are presented in Table II. The technical success rate showed a strong trend toward improvement in the IVUS-guided group (91.2% vs. 72.4%, $p = 0.051$). Among the cases of treatment failure in the IVUS guide group, there were 2 grade C cases and 1 grade D case according to the J-BTK scores. In the distal puncture group, there were 3 grade C cases and 5

Table I. Patients and lesion characteristics

	IVUS-first group	Distal puncture group	*P* value
Patients, *n*	34	29	
Age, y	76.0 ± 10.0	76.4 ± 9.1	0.87
Male, *n* (%)	22 (64.7)	19 (65.5)	0.95
BMI	22.6 ± 3.5	21.7 ± 3.8	0.31
Hypertension, *n* (%)	26 (76.5)	25 (86.2)	0.33
Hyperlipidemia, *n* (%)	21 (61.8)	18 (62.1)	0.98
Diabetes mellitus, *n* (%)	24 (70.6)	20 (69.0)	0.89
Smoking history, *n* (%)	17 (50.0)	16 (55.2)	0.68
Hemodialysis, *n* (%)	15 (44.1)	18 (62.1)	0.16
OMI, *n* (%)	7 (20.6)	10 (34.5)	0.22
Cerebral vascular disease, *n* (%)	6 (17.7)	7 (24.1)	0.53
ABI	0.46 ± 0.34	0.32 ± 0.32	0.11
Rutherford category			
4	0 (0)	2 (6.9)	0.12
5	30 (88.2)	26 (90.0)	0.86
6	4 (11.8)	1 (3.5)	0.22
Severe calcification, *n* (%)	16 (47.1)	19 (65.5)	0.14
Lesion length, mm	198.5 ± 80.6	234.8 ± 67.0	0.059
Occlusion length, mm	150.0 ± 70.0	154.1 ± 68.2	0.81
RVD, mm	2.45 ± 0.26	2.37 ± 0.20	0.24
J-BTK score			
A	5 (14.7)	1 (3.5)	0.13
B	11 (32.4)	13 (44.8)	0.31
C	16 (47.1)	10 (34.5)	0.31
D	2 (5.9)	5 (17.2)	0.15
GLASS IP grade			
3	3 (8.8)	1 (3.5)	0.38
4	31 (91.2)	28 (96.6)	0.38
GLASS IM			
P1	30 (88.2)	21 (72.4)	0.2
P2	4 (11.8)	8 (27.6)	0.2
Aspirin, *n* (%)	13 (38.2)	14 (48.3)	0.42
Clopidogrel, *n* (%)	28 (82.4)	19 (65.5)	0.13
Cilostazol, *n* (%)	5 (14.7)	1 (3.5)	0.13
Oral anticoagulant, *n* (%)	3 (8.8)	5 (17.2)	0.32

Values are mean ± SD or numbers (%), unless otherwise specified.
BMI, body mass index; RVD, reference vessel diameter; GLASS, Global Limb Anatomical Staging System; IP, infrapopliteal.

grade D cases. The complication rate was slightly lower in the IVUS-guided group, but there was no significant inter-group difference (5.9% vs. 13.8%, p = 0.29). Of the 34 cases in the IVUS-guided group, 24 (70.6%) were treated using IVUS-guided wiring alone, while 10 (29.4%) required the distal puncture technique. A complication—vascular perforation—occurred in only one of these 24 cases. In the subgroup analysis among lesions treated with an IVUS-first strategy, crossover to distal puncture occurred in 29.4% of cases. Severe calcification was significantly more frequent in the crossover group than in the IVUS-only group (90.0% vs. 29.2%, p = 0.002; Table III).

DISCUSSION

In this retrospective cohort study, an IVUS-first strategy was associated with a numerically higher technical success rate and a low complication rate and may help reduce the need for distal puncture. Furthermore, considering that a distal puncture was necessary without performing IVUS-guided wiring in cases where an antegrade approach by angiography-guided was difficult, it can be said that the incidence of distal punctures decreased.

There were many challenging cases of BTK CTO lesions, and it was often difficult to treat them by antegrade wiring alone via angiography.[8,9] The success rate of IVUS-guided wiring was slightly higher

Table II. Procedural and intervention results

	IVUS-first group ($n = 34$)	Distal puncture group ($n = 29$)	P value
Technical success, n (%)	31 (91.2)	21 (72.4)	0.051
Distal puncture rate, n (%)	10 (29.4)	29 (100)	<0.001
Procedural complication rate (%)	2 (5.9)	4 (13.8)	0.29
Flow-limiting dissection	0 (0)	0 (0)	
Wire perforation	2 (5.9)	2 (6.9)	
Distal embolization	0 (0)	0 (0)	
Unusual puncture site bleeding	0 (0)	0 (0)	

Table III. Comparison between IVUS-only and crossover groups among lesions treated with an IVUS-first strategy

	IVUS-only ($n = 24$)	Crossover ($n = 10$)	P value
Age, y	76.0 ± 8.7	77.3 ± 10.4	0.71
Hemodialysis, n (%)	9 (37.5)	6 (60.0)	0.28
Lesion length, mm	208.8 ± 78.1	174.0 ± 85.4	0.26
Occlusion length, mm	158.8 ± 67.8	129.9 ± 74.3	0.27
RVD, mm	2.47 ± 0.24	2.41 ± 0.33	0.57
Severe calcification, n (%)	7 (29.2)	9 (90.0)	0.002
J-BTK score C and D	10 (41.7)	8 (80.0)	0.041

Values are mean ± SD or numbers (%), unless otherwise specified.
RVD, reference vessel diameter.

than that of the distal puncture, possibly because the success rate of wire passage increased by firmly capturing the true lumen by assessing IVUS. In addition, it would also have been effective in cases of peripheral vascular bed insufficiency. Grade D J-BTK scores are associated with a 0% wire passage rate,[8] and the fact that the distal puncture group had slightly more cases of grade D might be one reason for this result. In this study, 70.6% of cases in which the distal puncture technique was considered were treated with IVUS-guided wiring from an antegrade approach alone. Hayakawa et al. reported that the success rate of the antegrade approach with IVUS-guided wiring alone was 63.1%, which was equivalent to the success rate in this study.[10] After factoring in the case that necessitated the distal puncture, this success rate was considered high.

In almost all cases, the Passable technique was used when IVUS-guided wiring was performed.[11] Although the second guidewire is often used as a tapered wire, delivery is difficult in cases of anterior tibial artery lesions due to their curvature. The Passable technique is instrumental for delivering the second guidewire to the vicinity of the first one. This technique is only possible with AnteOwl IVUS and is useful when performing IVUS-guided wiring on BTK lesions.

The distal puncture technique is useful and should be considered when an antegrade approach is not possible or fails to cross the lesion. However, the distal puncture technique requires caution due to the associated risk of complications.[12] IVUS-guided wiring does not cause distal puncture site complications, so fewer complications are expected with this technique than with the distal puncture technique. In this study, the complication rate was low among cases treated with IVUS-guided wiring alone. This technique is considered safe and useful, as it increases the likelihood of completing the procedure via the antegrade approach alone.

Although IVUS-guided wiring is considered a highly effective technique, it is not universal. The presence of severe calcification renders visibility on IVUS hard and prevents guidewire penetration. In addition, calcification may prevent the IVUS from passing through. This technique is likely to be difficult if the subintimal area becomes too large or if the blood vessel is narrow. The limitations of this technique include its dependence on the lesion characteristics and the skill of the EVT operator. Another limitation is that it is an antegrade intraluminal approach, which may require longer procedural durations.[5] The present study demonstrated that 29.4% of cases required distal puncture even

after IVUS-guided wiring. Procedural time and fluoroscopy time were not systematically collected in this retrospective analysis. Although IVUS-guided wiring may prolong procedural duration in certain cases, avoidance of distal puncture may offset additional time by reducing the need for retrograde access and puncture site management. Prospective studies are required to clarify the overall procedural efficiency of this strategy.

In recent years, IVUS has come to be used for BTK lesions to accurately evaluate vessel diameter and select the appropriate balloon.[13] Several studies reported that the use of IVUS for BTK lesions may improve wound healing rate and reduce the number of EVT procedures until wound healing is achieved compared to the use of EVT without IVUS.[14,15] This was because the balloon diameter was significantly larger in the IVUS-guided group than in the angio-guided group. Assessing the actual vascular diameter via IVUS makes it possible to select the optimal size of balloon diameter, allowing us to achieve better outcomes. Therefore, we should consider using IVUS not only for wiring but also for proper balloon dilatation.

IVUS-guided wiring for BTK CTO lesions was feasible and may reduce the need for distal puncture, corroborated by the reduction in distal puncture incidence. These findings provide practical insights into lesion selection for an IVUS-first strategy, suggesting that severe calcification may limit the success of antegrade-only completion.

However, due to the small number of cases in this study, further research using large-scale data should be conducted.

LIMITATIONS

This study has 4 major limitations: First, this was a single-center, retrospective study with a small number of patients; therefore, selection bias and recall bias may have affected the conclusion. Second, the choice between IVUS-guided wiring or distal puncture was left to the operator's discretion, as there was no predetermined protocol, which may have introduced selection bias. Third, this study included cases in which multiple lesions were treated simultaneously, and the procedure time and radiation exposure for single lesions are unknown. Fourth, the procedures were performed at a high-volume center by experienced operators, which may limit generalizability to less experienced settings. In addition, short-term outcomes, including 30-day clinical outcomes, were not systematically collected in this retrospective study. Furthermore, follow-up duration and reintervention rates were not assessed, which limits evaluation of the clinical impact beyond procedural success. Finally, as BTK arteries are often narrow, whether the procedure can be completed via only an antegrade approach will depend on the operator's proficiency in IVUS-guided wiring.

CONCLUSION

An IVUS-first strategy allowed antegrade-only completion in approximately 70% of BTK CTO lesions and may reduce the need for distal puncture in selected cases.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Yuki Shima: Writing — original draft, Investigation, Formal analysis, Data curation, Conceptualization. **Gakuto Bando:** Investigation. **Narumi Irie:** Investigation. **Kazunori Mushiake:** Investigation. **Hiroyuki Tanaka:** Writing — review & editing. **Mitsuru Abe:** Writing — review & editing.

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