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Investigation of the Feasibility and Safety of a Highly Intensive Penetration Technique for Recanalization in Severe Calcified Femoropopliteal Occlusive Lesions: A Retrospective Observational Study

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ABSTRACT

Background and Aims: When dealing with severely calcified lesions in endovascular therapy (EVT) for lower extremity artery disease (LEAD), navigating through severely calcified chronic total occlusion (CTO) using hard-tip guidewires can be challenging. To address this issue, we employed a novel highly intensive penetration (HIP) technique. This technique involves modifying the tail of a 0.035-inch guidewire to enhance its penetration capability, thus enabling effective navigation through the calcified lesion and facilitating the EVT procedure. This study aimed to assess the feasibility and safety of the HIP technique.

Methods: This single-center, retrospective study enrolled 27 consecutive patients (29 limbs) who underwent the HIP technique for the recanalization of calcified femoropopliteal CTO lesions that were resistant to penetration by high-tip load (≧40 g) guidewires between January 2015 and April 2023. Statistical analyses were performed using JMP 13 software.

Results: The mean patient age was 75.9 ± 10.1 years. The proportion of men, patients with hypertension, patients with diabetes mellitus, and patients on hemodialysis was 78%, 59%, 41%, and 44%, respectively. The crossover approach was selected for 55% of the patients. The reference vessel diameter was 5.3 ± 0.6 mm, and the lesion length was 19.7 ± 12.0 cm. The target lesions were predominantly located in the superficial femoral artery (76%). In-stent occlusion was treated in 14% of patients. The HIP technique was successfully performed in 79% of patients, and the complication rate of vascular perforation was 7%.

Conclusion: The HIP technique demonstrates remarkable effectiveness in navigating through highly calcified lesions, offering a reliable method for successful recanalization in challenging cases.

1 | Introduction

Owing to advances in technology and devices, endovascular therapy (EVT) has become increasingly used to treat patients with femoropopliteal artery disease [1]. However, challenges persist in EVT, particularly in the treatment of highly calcified lesions, where achieving long-term patency is difficult [2, 3], and passing a guidewire through the lesion is often challenging. Generally, high-tip load guidewires are used for passage attempts. However, if passage remains challenging, the knuckle wire technique may be utilized for subintimal wiring to circumvent calcification, followed by another attempt at guidewire

List of Abbreviations: CFA, common femoral artery; CTO, chronic total occlusion; EVT, endovascular therapy; HIP, highly intensive penetration; LEAD, lower extremity artery disease; PACSS, peripheral artery calcification scoring system; SFA, superficial femoral artery.

Summary

- Endovascular therapy (EVT) using a regular guidewire for the treatment of femoropopliteal lesions with severe calcification can be challenging.
- We devised the highly intensive penetration (HIP) technique to penetrate highly calcified femoropopliteal artery lesions that are otherwise difficult to penetrate by conventional EVT.
- The HIP technique demonstrates remarkable effectiveness in navigating through highly calcified lesions, offering a reliable method for successful recanalization in challenging cases

passage [4]. In cases where passing a general high-tip-load guidewire proves challenging, the PICKING technique [5], employing a 0.014- or 0.018-inch guidewire tail, has been reported. However, if the antegrade approach is unsuccessful, incorporating a retrograde approach can be an effective alternative [6].

In this study, we devised the highly intensive penetration (HIP) technique, specifically tailored for a 0.035-inch guidewire, to penetrate highly calcified femoropopliteal artery lesions. We aimed to investigate the feasibility and safety of this novel approach.

2 | Methods

This was a single-center, retrospective study. Among the patients who underwent EVT at our hospital between January 2015 and January 2023, we examined 27 consecutive patients in whom highly calcified femoropopliteal lesions were treated using the HIP technique (Figure 1).

The inclusion criteria were Rutherford 2–6 femoropopliteal lesions and highly calcified lesions that did not pass the conventional 0.014-inch hard-tip guidewire (tip load ≧ 40 g). We examined the procedural success and complication rates in these cases. The study protocol was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the local ethics committee of our hospital. Informed consent was obtained from all patients.

2.1 | Intervention

EVTs were performed using the ipsilateral or crossover approach. A 5- to 7-Fr sheath was inserted into the common femoral artery, and 5000 U of heparin was injected intra-arterially. If passing the lesion using hard-tip load guidewires (≧ 40 g) or crossing devices such as Crosser (BD, New Jersey), Wingman (Kaneka, Tokyo, Japan), or Truepath (Boston Scientific, MA, USA) was challenging, the HIP technique was used. Figure 2 illustrates the implementation of the HIP technique. The coating was carefully removed from the tail of a 0.035-inch Radifocus stiff guidewire (TERUMO Corporation, Tokyo, Japan) using clean needle-nose pliers (Figure 2A–C). Using the same pair of pliers, we proceeded to bend the tail (Figure 2D) and trimmed the bent tip to reduce its length (Figure 2E,F). Finally, we affixed a torque to the modified guidewire for procedural application. This approach enhanced maneuverability and facilitated the penetration of severely calcified femoropopliteal lesions.

A representative example is displayed in Figure 3. Lower limb angiography revealed a femoropopliteal lesion with severe calcification (Figure 3A). As the high-tip load 0.014-inch guidewire failed to navigate through the lesion, the HIP technique was effectively employed (Figure 3B). The HIP is withdrawn because catheters and devices often fail to follow it. A translucent image was observed within the calcification area corresponding to the site where the HIP technique was applied (Figure 3C, arrowhead). A 0.014-inch floppy guidewire was passed through this section (Figure 3D). A 0.035-inch hole was created within the calcification using HIP, enabling the balloon catheter to traverse smoothly. Stents were deployed following balloon dilatation, resulting in satisfactory dilation (Figure 3F).

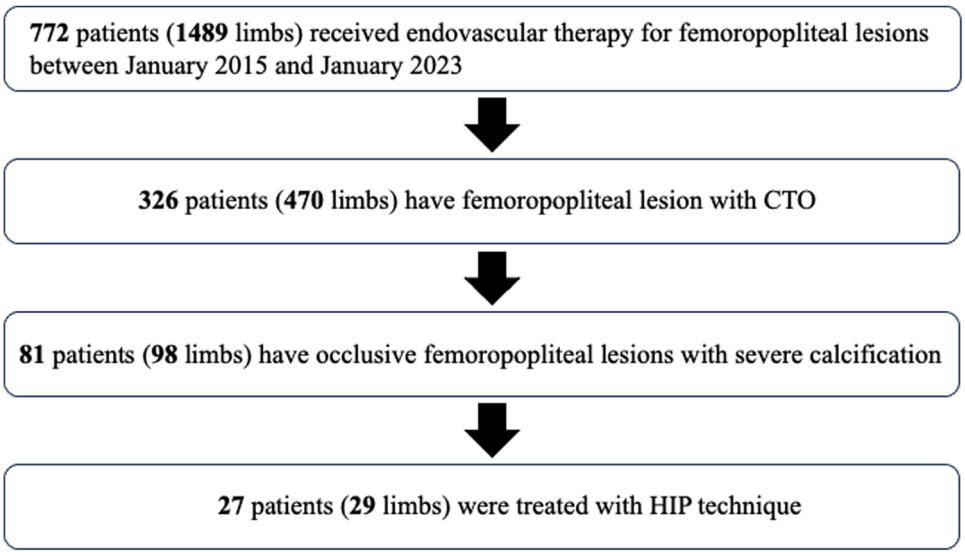

FIGURE 1 | Study participant flowchart.

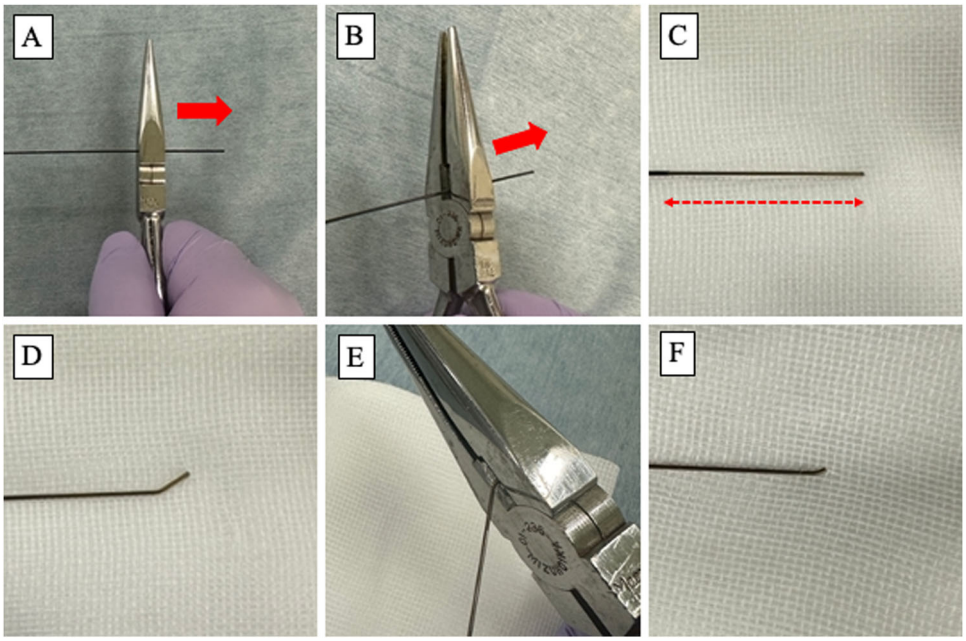

FIGURE 2 | Implementing the HIP technique.

2.2 | Definition

Technical success was defined as the successful passage of the guidewire through the lesion using the HIP technique. Procedural success was defined as achieving residual stenosis of $< 30\%$ without severe vessel dissection. Complications were defined as any adverse events, such as vascular perforation, occurring during the employment of the HIP technique. The peripheral artery calcification scoring system (PACSS) was used to evaluate the degree of lesion calcification on angiography. The PACSS classifies calcifications into five grades according to laterality and length: grade 0, no visible calcification of the target lesion site; grade 1, unilateral wall calcification < 5 cm; grade 2, unilateral calcification ≥ 5 cm; grade 3, bilateral wall calcification < 5 cm; and grade 4, bilateral calcification ≥ 5 cm [2, 3].

2.3 | Statistical Analysis

Statistical analyses were performed using JMP 13 software (SAS Institute Inc, Cary, NC, USA). Continuous variables are presented as mean $\pm$ standard deviation or median (interquartile range), whereas categorical data are presented as frequencies. The Shapiro–Wilk test is used for testing normality.

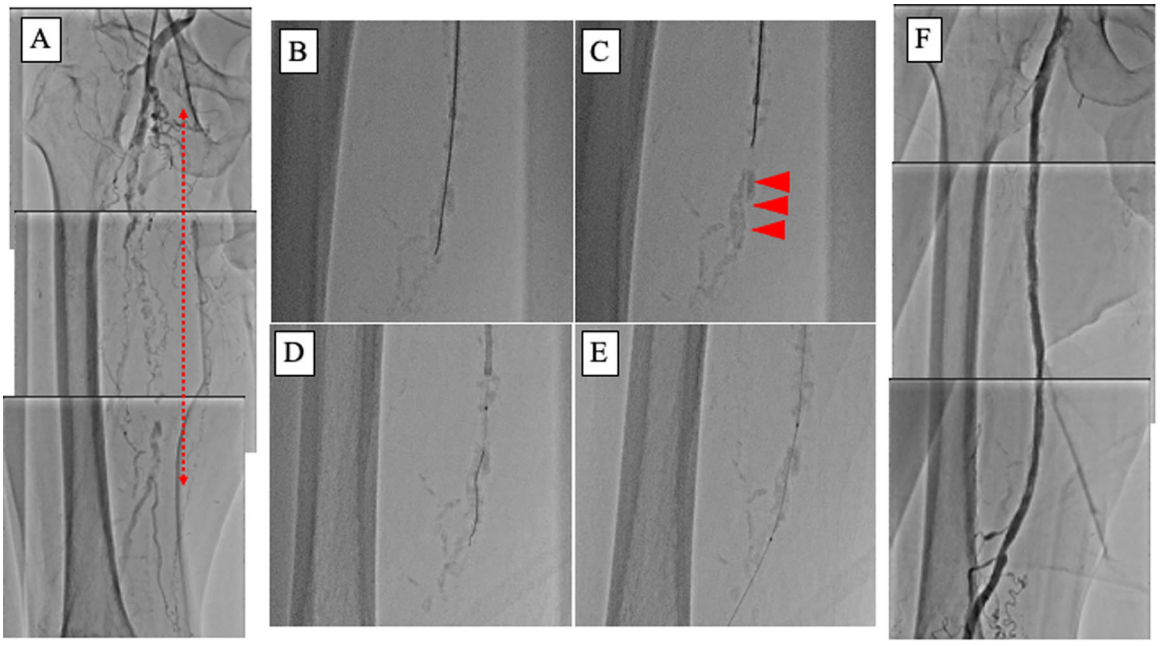

FIGURE 3 | Presentation of cases representative of the HIP technique.

TABLE 1 | Patient characteristics.

Variables	27 patients, 29 limbs
Age, years	75.9 ± 10.1
Male, n (%)	21 (78)
BMI[a], kg/m^2	21.7 ± 3.9
Hypertension, n (%)	16 (59)
Diabetes mellitus, n (%)	11 (41)
Dyslipidemia, n (%)	13 (48)
Hemodialysis, n (%)	12 (44)
Current smoker, n (%)	2 (7)
Coronary artery disease, n (%)	11 (41)
Cerebrovascular disease, n (%)	3 (11)
CLTI[b], n (%)	9 (33)
Medications	
Statin, n (%)	9 (33)
Aspirin, n (%)	20 (74)
P2Y12[c], n (%)	16 (59)
Cilostazol, n (%)	8 (30)
Approach	
Crossover approach, n (%)	16 (55)
Ipsilateral approach, n (%)	13 (45)
Target lesion	
Common femoral artery, n (%)	5 (17)
Superficial femoral artery, n (%)	22 (76)
Popliteal artery, n (%)	2 (7)
Vessel diameter, mm	5.3 ± 0.6
Lesion length, cm	19.7 ± 12.0
In-stent occlusion, n (%)	4 (14)
PACSS[d] grade 3, n (%)	10 (34)
PACSS grade 4, n (%)	19 (66)
Pre-ABI[e]	0.49 ± 0.29
Technical success, n (%)	23 (79)
Procedural success, n (%)	27 (93)
Distal puncture, n (%)	5 (17)
Crosser use, n (%)	7 (24)
Final device	
POBA[f], n (%)	5 (19)
DCB[g], n (%)	2 (7)
BNS[h], n (%)	9 (33)
DES[i], n (%)	7 (26)
IWS[j], n (%)	2 (7)
SG[k], n (%)	2 (7)
Total procedure time, min	210 (IQR[l]: 141–288)
Contrast media, mL	137 ± 55
Radiation exposure, mGy	309 (IQR: 171–422)
Complication rate, n (%)	2 (7)

[a]Body mass index.
[b]Chronic limb-threatening ischemia.
[c]antiplatelet inhibitor.
[d]peripheral artery calcification scoring system.
[e]ankle-brachial index.
[f]plain old balloon angioplasty.
[g]drug-coated balloon.
[h]bare nitinol stent.
[i]drug-eluting stent.
[j]interwoven stent.
[k]stent graft.
[l]interquartile range.

3 | Results

The baseline patient characteristics are shown in Table 1. The mean age was 75.9 ± 10.1 years. The proportions of male patients and patients with hypertension, diabetes mellitus, and hemodialysis were 78%, 59%, 41%, and 44%, respectively. The crossover approach was selected for 55% of the patients. The target lesions were the common femoral artery (CFA), superficial femoral artery (SFA), and popliteal artery in 17%, 76%, and 7% of the patients, respectively. In-stent occlusion was treated in 14% of the patients. The reference vessel diameter was 5.3 ± 0.6 mm, and the lesion length was 19.7 ± 12.0 cm.

Technical success was achieved in 79% (23/29) of cases. Among cases where the HIP technique was unsuccessful, three were attributed to its inability to navigate the curve of the CFA, whereas the remaining three were hindered by calcification. Ultimately, the procedure proved successful in 93% of cases (27 out of 29), with the remaining two cases requiring surgical revascularization. The complication rate associated with the HIP technique was 7%, with vascular perforation occurring in two of the 29 cases. In one case, bleeding was stopped using a stent graft. In the other case, bleeding was stopped by long balloon inflation. No blood transfusion was required in either case.

4 | Discussion

The study evaluated the HIP technique, which modifies the tail of a 0.035-inch guidewire to improve penetration through severely calcified femoropopliteal CTO lesions. As the first report on this technique, the study demonstrated the feasibility and safety of HIP for recanalizing challenging lesions in EVT.

When treating femoropopliteal lesions with severe calcification, a regular guidewire is initially employed. If the guidewire fails to pass the lesion, it is substituted with a high-tip load guidewire in an attempt to penetrate the lesion [4]. If this is unsuccessful, we often resort to subintimal wiring from either the antegrade or retrograde regions. At this juncture, a re-entry device, such as the Outback (Cardinal Health, USA), facilitates

controlled antegrade and retrograde subintimal tracking to re-enter the guidewire from the subintimal space to the intimal space [7]. Additionally, various crossing devices, including the Crosser, Wingman, and Truepath, can be used to traverse severely calcified lesions, with their efficacy previously reported [8–11]. These devices are expensive, and occasionally, even these crossing devices are ineffective against severely calcified lesions.

Kawarada et al. previously reported the PICKING technique, which uses a 0.014- or 0.018-inch guidewire tail, as an inexpensive and highly effective method for passing a guidewire through severely calcified lesions [5]. However, visualizing the tails of the 0.014- and 0.018-inch guidewires under fluoroscopy is challenging, and it is difficult for devices such as balloon catheters to pass through the lesion after the wires have traversed it. In contrast, the HIP technique offers excellent visibility owing to the 0.035-inch guidewire. Additionally, after the guidewire passes, a 0.035-inch (= 2.7 Fr equivalent) hole is created within the calcification, facilitating the passage of devices such as balloons.

However, an extremely high tip load poses a potential risk of vascular perforation. Careful proceeding is essential when checking for calcification using fluoroscopy in two directions and palpating for calcification. Conversely, we believe that the HIP technique is unsuitable for cases where the path of calcification is not observable under fluoroscopy.

Furthermore, the HIP technique is unlikely to be effective for curved lesions such as CFA lesions due to the excessive rigidity of the guidewire, causing it to veer towards the greater curvature side of the bent portion and not advance if calcification is present on the lesser curvature side. This limitation also applies when using a catheter with a curved tip for support; the rigidity of the guidewire causes the curvature at the tip of the catheter to straighten out, often rendering it ineffective. In this study, several instances where this approach failed to yield success were observed.

For highly calcified lesions in the CFA, it is preferable to puncture the calcification directly from outside the body, as reported by Hayakawa et al. [12] We also recommend using the HIP technique on relatively straight sections of the SFA.

In this study, a crossover approach was employed in 55% of cases; however, if the angle of the iliac bifurcation is steep, the HIP technique may potentially break through the sheath. In such instances, performing a crossover while safeguarding the modified tip of the guidewire used in the HIP with a guide or guide extension catheter is essential. Alternatively, avoiding the use of the HIP technique entirely may be a more suitable course of action.

4.1 | Limitations

This study had some limitations. First, it was a retrospective analysis with a relatively small sample size from a single hospital. Second, the decision to employ the HIP technique following the unsuccessful passage of the high-tip load guidewire relied on the discretion of the operator. Third, this was a single-arm study and did not compare outcomes with other techniques or devices. Therefore, future studies are needed to investigate the comparative effectiveness of the HIP technique in larger, multicenter cohorts to further standardize its utility in managing severely calcified femoropopliteal artery lesions.

5 | Conclusion

Data of this small study suggests safety and feasibility of the HIP technique in treating femoropopliteal artery lesions with severe calcification. This technique may be used for severely calcified lesions where a standard hard-tip 0.014-inch GW would not pass through.

Author Contributions

Shinsuke Mori: conceptualization, data curation, formal analysis, investigation, methodology, writing–original draft, writing–review & editing. **Keisuke Hirano:** conceptualization, supervision, writing–review & editing. **Yusuke Setonaga:** data curation. **Toshihiko Kishida:** data curation. **Tomoya Fukagawa:** data curation. **Kohei Yamaguchi:** data curation. **Masafumi Mizusawa:** formal analysis, investigation. **Masakazu Tsutsumi:** formal analysis, investigation. **Norihiro Kobayashi:** supervision, writing–review & editing. **Yoshiaki Ito:** project administration, supervision, writing–review & editing.

Acknowledgments

The authors have nothing to report.

Ethics Statement

The study protocol was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the local ethics committee of each hospital. Informed consent was obtained from all patients.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Data and materials cannot be shared openly to protect the patient's privacy.

Transparency Statement

The lead author Shinsuke Mori affirms that this manuscript is an honest, accurate, and transparent account of the study being reported, that no important aspects of the study have been omitted, and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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