BMJ Open

Safety and effectiveness of the Chocolate balloon catheter in the treatment of peripheral artery disease with percutaneous transluminal angioplasty: a multicentre, prospective, observational study protocol

Zi-Qiu Ye ,[1] Hanyi Liu,[2] Xin Fang,[2] Xiao-Hu Meng[2]

To cite: Ye Z-Q, Liu H, Fang X, *et al*. Safety and effectiveness of the Chocolate balloon catheter in the treatment of peripheral artery disease with percutaneous transluminal angioplasty: a multicentre, prospective, observational study protocol. *BMJ Open* 2025;**15**:e103906. doi:10.1136/bmjopen-2025-103906

► Prepublication history for this paper is available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2025-103906).

Received 18 April 2025
Accepted 18 September 2025

Check for updates

© Author(s) (or their employer(s)) 2025. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ Group.

[1]The Fourth School of Clinical Medicine, Zhejiang Chinese Medical University, Hangzhou First People's Hospital, Hangzhou, Zhejiang, China
[2]Department of Vascular Surgery, Hangzhou First People's Hospital, Hangzhou, Zhejiang, China

Correspondence to
Xiao-Hu Meng;
15968116449@163.com

ABSTRACT

Background Peripheral artery disease (PAD) represents a significant global health burden. Percutaneous transluminal angioplasty (PTA) is the most commonly employed endovascular intervention; however, its long-term efficacy is often compromised by restenosis and flow-limiting dissection. The Chocolate balloon catheter, characterised by a nitinol-constrained design that enables controlled, segmental vessel dilation, has demonstrated potential in minimising vascular trauma and enhancing patency. Nevertheless, there remains a lack of robust multicentre evidence evaluating its safety and effectiveness in real-world Chinese PAD populations. This protocol outlines a prospective, multicentre, single-arm observational study aiming to assess the 12 month primary patency and complication rates following Chocolate balloon PTA in Chinese patients with femoropopliteal or infrapopliteal lesions.

Methods and analysis This prospective, multicentre, single-arm observational study will be conducted across eight medical centres in China. Eligible patients with symptomatic PAD (Rutherford classification 2–5) and de novo or restenotic lesions in the femoropopliteal or infrapopliteal arteries, for whom the use of a Chocolate balloon catheter is indicated as per standard care, will be enrolled. All participants will undergo percutaneous transluminal angioplasty using the Chocolate balloon catheter and will be followed up for 12 months. The primary outcome is the primary patency rate of the target lesion at 12 months, defined as the absence of restenosis (diameter stenosis <50% by duplex ultrasound with a peak systolic velocity ratio <2.5) and freedom from target lesion revascularisation.

Ethics and dissemination The study protocol was approved by the Clinical Trial Ethics Committee of Hangzhou First People's Hospital (Approval No. IIT-20220606-0082-01). The findings will be disseminated in peer-reviewed publications.

Trial registration number NCT06933992.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a prospective, multicentre observational study designed to reflect real-world clinical practice.
⇒ The study employs independent core laboratory adjudication for key imaging endpoints to minimise bias.
⇒ The inclusion of patients with a range of lesion complexities (Transatlantic International Society Consensus A–D) enhances generalisability.
⇒ A limitation is the single-arm design without a control group, which prevents direct comparative effectiveness inferences.
⇒ Investigator and patient preference in treatment selection may introduce selection bias.

INTRODUCTION

In the management of peripheral arterial disease (PAD), conventional percutaneous transluminal angioplasty (PTA) is a widely adopted intervention.[1] However, its clinical efficacy at 1 year is often undermined by complications such as restenosis and vascular dissection.[2–4] Clinical data indicate that approximately 15–20% of patients experience restenosis within 1 year following conventional PTA, significantly compromising treatment outcomes and imposing additional economic and psychological burdens on patients. Especially for arterial segments with severe calcification, traditional balloon dilation techniques face higher challenges.[4]

Although Plain Old Balloon Angioplasty (POBA) is widely used in the treatment of arterial stenosis, it also has significant limitations. For example, although POBA can rapidly expand vascular segments with stenosis, restenosis may occur within a period of time after the operation due to intimal hyperplasia or elastic recoil.[4] This situation is particularly common in the lower limb arteries and often requires repeated interventions. Therefore,

BMJ Open: first published as 10.1136/bmjopen-2025-103906 on 13 October 2025. Downloaded from http://bmjopen.bmj.com/ on November 18, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

reducing the problem of restenosis after the operation remains a pressing issue.

The Chocolate balloon catheter stands out by virtue of its unique design. It adopts a special structure that can expand blood vessels while reducing damage to the vessel wall.[5] In theory, this design provides a better vascular pretreatment effect and helps reduce the risk of restenosis. Preliminary studies show that this new type of balloon can more evenly expand the arteries during the treatment process while reducing the risk of dissection and other complications that traditional balloons may cause.[5] According to the latest research and reports, the Chocolate Balloon has shown good therapeutic effect and safety in the treatment of peripheral vascular diseases, especially femoropopliteal artery lesions.[6] However, there are still many limitations in the current research on the therapeutic effect and safety of the chocolate balloon for the treatment of lower limb atherosclerotic lesions. The existing evidence is not yet sufficient to provide conclusive support for its long-term therapeutic effect and safety. For example, the research may be affected by factors such as small sample size, short follow-up time or lack of a control group. Therefore, despite the encouraging preliminary results, further large-scale, multicentre, randomised controlled trials are still needed to verify the true value and scope of application of chocolate balloons in the treatment of peripheral arterial disease.

Although some early studies and clinical trials have shown the potential advantages of chocolate balloon catheters, such as improving the success rate of vascular opening and reducing the incidence of complications after the operation,[7 8] their long-term safety and effectiveness still need to be further validated. The current research plan adopts a multicentre, prospective, randomised controlled trial to compare the therapeutic effect of using chocolate balloon catheters with traditional balloon catheters for percutaneous transluminal angioplasty in the treatment of PAD.

This study aims to provide robust observational data on the safety and effectiveness of the chocolate balloon catheter in a real-world, multicentre setting. It will evaluate technical success, primary patency, clinical improvement and safety outcomes over a 12-month period, contributing to the evidence base for this device in the treatment of PAD.

METHODS AND ANALYSIS

Study design and setting

This prospective, multicentre, single-arm, observational study will be conducted at eight vascular centres in China. The planned study period is from 1 September 2025 to 30 September 2027.

Study hypothesis

This study aims to verify whether the chocolate balloon catheter can demonstrate acceptable safety and effectiveness profiles during a 12-month follow-up period when used in percutaneous intravascular angioplasty for the treatment of lower limb atherosclerotic plaque lesions, as measured by primary patency and complication rates against pre-specified performance goals derived from historical data.

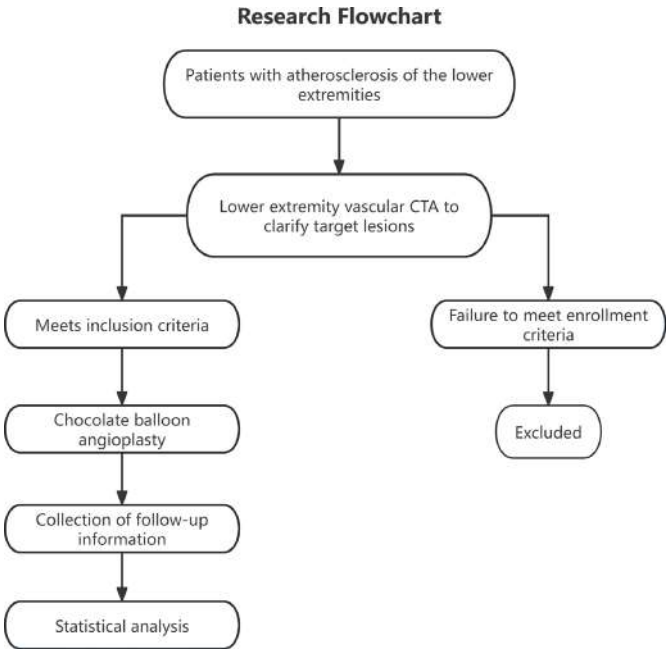

Figure 1 Flowchart of the clinical trial design. CTA, computed tomography angiography.

Recruitment

Participants will be recruited from eight participating medical centres across China. Figure 1 summarises the entire research process. Eligible patients aged 18 to 80 years with symptomatic PAD (Rutherford classification 2–5) and suitable femoropopliteal or infrapopliteal lesions, for whom Chocolate balloon angioplasty is indicated as per standard care, will be enrolled. Recruitment is scheduled to begin on 1 September 2025 and will continue until the target sample size of 171 patients is reached.

Inclusion criteria

1. The subjects or their guardians have been informed of the nature of this study and agreed to participate in this study, and the subjects or their guardians have signed the informed consent.
2. Aged ≥18 and ≤80 years.
3. Presence of chronic, symptomatic lower limb ischaemia defined as Rutherford Classification Category 2, 3, 4 or 5.
4. The primary target lesion(s) must be located in the native superficial femoral, popliteal and/or infrapopliteal arteries, with SFA/popliteal lesions of any Transatlantic International Society Consensus (TASC) II class (A–D) permitted.
5. The patient must be judged by the vascular team to be an appropriate candidate for percutaneous transluminal angioplasty, and the Chocolate balloon catheter

BMJ Open: first published as 10.1136/bmjopen-2025-103906 on 13 October 2025. Downloaded from http://bmjopen.bmj.com/ on November 18, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

must be considered—on the basis of lesion morphology and clinical presentation—a standard-of-care option for that individual.
6. Researchers assess lifespan >1 year.

Exclusion criteria

1. Diagnosis of active systemic infection or uncontrolled coagulation dysfunction within 14 days before the operation.
2. The plan is to perform a major amputation at the target limb (amputation plane located at the ankle joint or higher).
3. Patients with renal insufficiency or chronic kidney disease with MDRD (Modification of Diet in Renal Disease) GFR (glomerular filtration rate) ≤30 mL/min/1.73 m^2 (or serum creatinine ≥2.5 mg/dL within 30 days before the operation, or receiving dialysis treatment).
4. Unable to take medication as required by the plan, or allergic to antiplatelet drugs (aspirin or clopidogrel), low molecular weight heparin, vasodilators or contrast agents, resulting in inability to fully comply with medication treatment requirements before and after the operation.
5. Uncontrolled systemic diseases, such as severe cardiac, pulmonary or hepatic dysfunction; advanced cancer; cachexia; severe unrelieved symptoms of coronary heart disease; or genetic coagulation disorders.
6. In the past 6 months, cerebral haemorrhage, symptomatic stroke, myocardial infarction, gastrointestinal bleeding.
7. Women who are breastfeeding or pregnant, or women or men who are planning to conceive in the near future.
8. Currently participating in another interventional clinical study, and the primary endpoint has not yet been reached.
9. Researchers believe that there are other factors that make the subjects unsuitable for participating in this study, including but not limited to medical, social or psychological issues.
10. Life expectancy <1 year.

Baseline assessment

Patients will be assessed immediately after confirmation of initial eligibility and written informed consent. The baseline evaluation will include age, height, weight, medical history, full blood count, serum chemistry, C-reactive protein, ankle–brachial index, Rutherford classification, duplex ultrasonography of the target lesion and core-lab adjudicated angiographic imaging.

Intervention

All participants will undergo PTA with a Chocolate balloon catheter under standard anticoagulation and dual antiplatelet therapy, followed by 12 months of clinical and imaging surveillance; clinic visits at 1, 3, 6 and 12 months; and telephone follow-up at 9 months. Assessments include ankle-brachial index (ABI), Rutherford class, duplex ultrasonography, medication use and adverse events. Angiographic assessments are at 1 and 12 months.

Access is obtained via the femoral artery using the Seldinger technique. After angiography, an appropriate guidewire is advanced across the lesion. A Chocolate balloon (diameter-to-vessel ratio 1:1) is advanced and inflated at 4–8 atm for 30–60 s. Post-procedural angiography evaluates residual stenosis; bail-out stenting is performed if residual stenosis is >30%, flow-limiting dissection is ≥grade C, pressure gradient is ≥10 mm Hg or acute occlusion occurs.

Lower limb arterial imaging and remedial stenting

During lower-limb arterial intervention, the operator will select the most informative imaging modality (angiography, OCT or IVUS). Bail-out bare-metal stenting is performed only when at least one of the following criteria is met: (1) core-lab quantitative angiography shows residual diameter stenosis >30%, (2) imaging-confirmed flow-limiting dissection ≥grade C, (3) trans-lesional mean pressure gradient ≥10 mm Hg after balloon deflation or (4) acute vessel occlusion or impending vessel closure. In these situations, a self-expanding bare-metal stent (preferred for its radial strength and biocompatibility) is implanted to restore and maintain patency and to minimise restenosis risk.

Study endpoints

Primary endpoint

The primary outcome is the 12-month primary patency rate of the target lesion, analysed per protocol (all participants who completed the Chocolate balloon angioplasty and provided duplex ultrasound data). Primary patency is defined as the absence of restenosis (based on duplex Doppler ultrasound criteria: diameter stenosis <50% and peak systolic velocity ratio <2.5) and freedom from target lesion revascularisation (TLR). A core-lab ultrasonographer blinded to centre and procedural details will adjudicate every duplex study; an independent clinical-events committee blinded to imaging will adjudicate any TLR.

Secondary endpoints

1. Freedom from clinically driven TLR at 1, 6 and 12 months after the operation.
2. Rate of acute angiographic success: core-laboratory adjudicated residual stenosis ≤30% and absence of flow-limiting dissection (grade D or higher) immediately after device deployment.
3. Rate of bailout stenting: proportion of cases requiring emergency stent placement due to sub-optimal balloon angioplasty results (severe dissection, recoil or residual stenosis).
4. Improvement in the Rutherford clinical category by ≥1 class from baseline at each follow-up time point.
5. Increase in ABI ≥0.15 from baseline at each follow-up time point.

BMJ Open: first published as 10.1136/bmjopen-2025-103906 on 13 October 2025. Downloaded from http://bmjopen.bmj.com/ on November 18, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

6. Increase in toe-brachial index from baseline at each follow-up time point.

Safety endpoints

1. Device-oriented safety endpoint: Incidence of device-related or procedure-related serious adverse events through 30 days post-procedure.
2. All-cause mortality through 12 months.
3. Major adverse limb events through 12 months, including major amputation and major reintervention.
4. Peri-procedural complication rate (within 30 days), encompassing access-site events (haematoma, pseudoaneurysm and AV fistula), distal embolisation, vessel perforation/rupture, ≥type D dissection needing intervention, acute limb ischaemia, contrast-induced nephropathy and major bleeding (Bleeding Academic Research Consortium (BARC) 2, 3 or 5).

Medications

According to the latest clinical guidelines and local medical practices, all patients participating in the study will receive dual antiplatelet therapy for 1 to 3 months before the operation. The recommended regimen is to take an enteric-coated aspirin tablet (brand name: Aspirin Protect), 100 milligrams, and clopidogrel bisulfate tablet (brand name: Plavix), 75 milligrams orally once on a daily basis. During the operation, heparin or other appropriate anticoagulants will be used for management. After the operation, it is recommended that patients take 100 milligrams of enteric-coated aspirin (Aspirin Protect) once daily for the long term; at the same time, continue to take clopidogrel hydrogen sulfate tablets (Plavix) 75 milligrams once daily for at least 12 months. During this period, it is necessary to closely monitor any signs of bleeding from the gums, urine and so on and to regularly recheck the blood routine and coagulation function 1 month after the operation, as well as assess the risk of bleeding through D-dimer testing, to ensure timely detection and management of possible complications.

Follow-up

All clinical endpoints will be assessed at 1, 3, 6 and 12 months after the index Chocolate balloon procedure; duplex ultrasound evaluation of the target lesion will be performed at 1, 6 and 12 months (±7 days window) by a core-lab sonographer blinded to treatment and centre. Every follow-up visit will be used to confirm and record all research endpoints, ensuring comprehensive tracking of long-term efficacy and safety. To guarantee objectivity and accuracy, independent clinical research coordinators will supervise the entire follow-up process, document any treatment-related clinical events and verify that all data are collected and analysed correctly.

Data collection and management

Researchers received specialised reinforcement training to improve the quality and consistency of data collection and will be responsible for both data collection and input tasks. Data management is centrally carried out by the Hangzhou First People's Hospital to ensure the standardisation and efficiency of data processing. At each participating medical centre, researchers will collect detailed data required for this clinical study, including but not limited to patients' baseline clinical characteristics, medication treatment records, laboratory test results, intervention treatment processes and their outcomes. All text data will be accurately entered into the advanced data management system. In order to protect patient privacy, all transmitted data will be anonymised. To ensure the integrity and traceability of the data, all collected data will be retained for at least 10 years. In addition, an independent Data Monitoring Committee (DMC) has been established to review the accuracy of the data quarterly, ensuring the authenticity and reliability of the data.

Trial status

The clinical trial is currently underway, with participants being recruited at 8 medical centres in China. The target number of subjects for each centre is set based on the centre's patient admission situation and specific requirements. All patients must meet the inclusion criteria of the trial and not violate any exclusion criteria.

Sample size and statistical analyses

Based on Zhong *et al*, the target-lesion re-intervention rate after plain balloon angioplasty is approximately 32%, whereas the expected rate after Chocolate balloon dilatation is 21%, implying a 79% 12-month primary patency.[9] We therefore set a pre-specified performance goal of 70% patency, consistent with historical POBA data for comparable lesions. With a one-sided α of 0.025 and 90% power, 140 evaluable patients are required to reject a null patency rate of 70% in favour of the anticipated 79%. Allowing for 10% loss to follow-up, we will enrol a minimum of 171 subjects.

The calculation formula is as follows:

$$n = p_0(1-p_0)\left(\frac{z_{1-\alpha}+z_{1-\beta}\sqrt{\frac{p(1-p)}{p_0(1-p_0)}}}{p-p_0}\right)^2$$

$$1-\beta = \Phi\left(\sqrt{\frac{p_0(1-p_0)}{p(1-p)}}\left(\frac{|p-p_0|\sqrt{n}}{\sqrt{p_0(1-p_0)}} - Z_{1-\alpha}\right)\right)$$

N is sample size ; p0 is the comparison value ; Φ is the standard normal distribution function ; α is Type I error ; β is Type II error ; δ is the testing margin ; significance level and power of clinical research: α=0.025, 1-β=0.9.

All statistical analyses will be performed with SPSS 24.0 (IBM Corp., USA). Because the study is single-arm, inferential comparisons between groups are not planned; analyses will be descriptive and centred on estimation with 95% confidence intervals. Continuous variables will first be tested for normality (Kolmogorov–Smirnov); normally distributed data will be summarised as mean±SD and non-normally distributed data as median (IQR), while categorical variables will be presented as frequencies and percentages. Time-to-event outcomes (primary patency,

BMJ Open: first published as 10.1136/bmjopen-2025-103906 on 13 October 2025. Downloaded from http://bmjopen.bmj.com/ on November 18, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

freedom from TLR) will be estimated with the Kaplan–Meier method and displayed with 95% CIs; no log-rank or Cox comparisons are prespecified. A p value <0.05 will be considered statistically significant for any exploratory analyses that may be reported.

Patient and public involvement

Patients and the public were not involved in the development of the research questions, selection of endpoint measures, study design, patient recruitment or conduction of the study. The burden of intervention was assessed by representatives of patient associations participating in the ethical review committee. As mentioned in the individual consent form, participants may obtain access to the final results of the study through the principal investigator.

DISCUSSION

PAD is a chronic occlusive arterial disease caused by the accumulation of plaques within the arterial lumen, leading to reduced blood flow. It is one of the most common manifestations of systemic atherosclerosis, affecting nearly 20% of people over 70 years old.[10 11] Over the past 20 years, disability and mortality rates related to PAD have increased and are no longer limited to the elderly population, now also including young adults.[12] In 2010, there were 202 million people worldwide suffering from PAD.[13] The popliteal artery is the most common site of occlusive disease, and lower limb PAD is the third leading cause of atherosclerotic cardiovascular disease after cardiovascular disease and stroke.[14] Approximately 15–30% of lower limb PAD patients will progress from intermittent claudication (IC) to critical limb ischaemia (CLI)[15 16] and will require some form of percutaneous or surgical intervention for revascularisation. Most of the time, the first and sole clinical manifestation of PAD presents as IC, and the prognosis of patients with intermittent claudication depends on cardiovascular or cerebrovascular complications. When the CLI risk of IC patients is very low: no more than 5% of PAD patients will develop CLI with rest pain or gangrene,[17] 25% of patients will worsen with increasing walking distance, and 50% of patients will remain clinically stable.[15] In most cases, IC is maintained by isolated movements of the gastrocnemius area. Changing risk factors, treating complications and exercising under supervision are basic treatment methods. Current international guidelines consider conservative treatment as the first-line treatment for all IC patients,[18 19] and surgical treatment methods should be only reserved for patients whose IC-related symptoms cannot be relieved. According to the TASC,[20] it is recommended to perform the endovascular operation for type A and type B lesions and surgical repair for type C and type D lesions. However, given the high incidence of complications and mortality after the operation,[20] nowadays, for all IC patients requiring surgical treatment, regardless of TASC classification, endovascular methods are considered a reliable first-line treatment.[21] Therefore, PTA has become the preferred treatment method for most patients. Unfortunately, even the use of drug-coated balloons (DCB), simple PTA will be accompanied by acute complications after standard balloon inflation and deflation. These complications are related to vascular injury, which can lead to vascular flow-limiting dissection or unsatisfactory results of vascular angioplasty, usually requiring remedial stent implantation, with implantation rates as high as 40% in different series.[22–24] In addition, the presence and extent of calcification increase the complexity of treating these lesions.[25 26] The most closely related risk factors for vascular calcification are old age, diabetes, chronic kidney disease and high blood pressure.[27] A recent study has shown that at least one vascular bed in elderly people over 70 years old contains vascular calcifications, with two-thirds having calcifications in all arterial beds.[28] Angiography is used to help determine the appropriate strategy for percutaneous treatment of PAD, but studies have shown that angiography underestimates the level of vascular calcification, so this issue is worth paying attention to.[29] Calcification increases the risk of vascular complications after angioplasty or stent placement, including dissection, perforation, distal embolisation, TLR and restenosis.[30–33] Traditional interventional therapy for PAD continues to result in complications, including acute surgical failure and long-term restenosis. The acute surgical failure is due to incomplete vascular dilation and the persistent presence of highly stenosed or blood flow-restrictive dissection, both of which occur in the context of high complexity and severity of vascular calcification. In these situations, it is necessary to use emergency stents containing metal implants to ensure vascular patency. Although randomised trials have shown that the early patency rate of stents is higher compared with PTA alone,[34–36] the long-term results are still influenced by the significant incidence of complications.[37 38] All of the above factors prompt doctors to avoid stent implantation whenever feasible, opting instead for a new strategy that involves appropriate vessel preparation using PTA or atherectomy devices before drug delivery via DCB.[21] Chocolate PTA balloon catheter (TriReme Medical LLC, Pleasanton, California, USA) is a standard balloon catheter constrained by a nitinol stent, which can segment the balloon during balloon expansion, thereby forming recesses and grooves on the balloon surface, thereby increasing the contact surface area of the Chocolate balloon catheter. This balloon design is intended to disperse the increased contact surface force associated with angioplasty, resulting in controlled and differentiated expansion, in order to minimise overall vascular trauma. This study aimed to investigate the safety and effectiveness of the Chocolate Balloon Catheter in percutaneous transluminal angioplasty for peripheral arterial disease.

BMJ Open: first published as 10.1136/bmjopen-2025-103906 on 13 October 2025. Downloaded from http://bmjopen.bmj.com/ on November 18, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Strengths and limitations of study

This trial has several important advantages. First, as a prospective, multicentre study, it covers a broader patient population and clinical practice setting, thereby increasing the general applicability and external validity of the results. The study objectives were clearly defined and aimed to evaluate the efficacy and safety of chocolate balloon intervention for the treatment of lower extremity arterial disease. Second, the design of the inclusion and exclusion criteria allowed this study to accurately reflect current standard operating procedures for lower extremity arterial disease in vascular surgery practice. This not only ensured the authenticity and utility of the study, but was further strengthened by the high proportion of patients enrolled after screening. In addition, to ensure the quality and consistency of the data, all participating investigators received special training, and a single organisation was responsible for data management, achieving standardisation and efficiency in data processing. During the data collection process, clinical outcomes, complications and adverse events were structured, recorded and monitored, especially at short time intervals, which improved the accuracy and reliability of the data.

However, some shortcomings must be acknowledged. The lack of randomisation and a placebo control group may have introduced an attrition bias, which may affect the accurate assessment of treatment effects. Patient selection may be influenced by the subjective judgement of the investigator or by the patient's own preferences. In addition, a non-blinded study design may lead researchers to be influenced by their own expectations when assessing treatment effects, increasing the likelihood of bias. To minimise this bias, it is suggested that non-researchers be used for data entry in the pre-study phase to ensure as much objectivity as possible in data assessment. These measures will help to improve the overall quality and credibility of the trial.

Ethics and dissemination

This study involves human participants and was approved by the Clinical Trial Ethics Committee of the First People's Hospital of Hangzhou (Approval No. IIT-20220606-0082-01). All participating centres recognised this approval. Written informed consent will be obtained from every enrolled patient.

Contributors Z-QY conceived and prepared the manuscript. HL and XF performed the experiments, collected the data and analysed and interpreted the data. X-HM provided funding support. X-HM and XF are co-corresponding authors and contributed equally to this work. X-HM is the guarantor and accepts full responsibility for the work and the conduct of the study, had access to the data and controlled the decision to publish. All authors read and approved the final draft.

Funding This work is supported by Hangzhou bio-medicine and health industry development science and technology project grant numbers 2024WJC105.

Disclaimer All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organisations or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iD

Zi-Qiu Ye http://orcid.org/0009-0006-2253-6668

REFERENCES

1 Robertson L, Paraskevas KI, Stewart M. Angioplasty and stenting for peripheral arterial disease of the lower limbs: an overview of Cochrane Reviews. *Cochrane Database Syst Rev* 2017.
2 Yu H, Chi Y, Wang B. The efficacy of percutaneous transluminal angioplasty and arteriovenous fistula reconstruction for immature arteriovenous fistula. *BMC Nephrol* 2023;24:304.
3 Iwashima Y, Fukuda T, Yoshihara F, *et al*. Incidence and risk factors for restenosis, and its impact on blood pressure control after percutaneous transluminal renal angioplasty in hypertensive patients with renal artery stenosis. *J Hypertens* 2016;34:1407–15.
4 Gobbi C, Giangiacomi F, Merinopoulos I, *et al*. Drug coated balloon angioplasty for de novo coronary lesions in large vessels: a systematic review and meta-analysis. *Sci Rep* 2025;15:4921.
5 Wu R, Yang Q, Wang M, *et al*. Safety and efficacy of chocolate balloon in the treatment of infrapopliteal artery disease. *CVIR Endovasc* 2025;8:39776384.
6 Böhme T, Zeller T, Shishehbor MH, *et al*. Chocolate Touch Versus Lutonix Drug-Coated Balloon for Femoropopliteal Lesions in Diabetes: The Chocolate Touch Study. *J Endovasc Ther* 2025;32:414–22.
7 Shishehbor M, Zeller T, Holden A. TCT-775 Results of the First-in-Human Chocolate Touch Drug-Coated Balloon Catheter - ENDURE Trial. *J Am Coll Cardiol* 2016;68:B313.
8 Cheng C-I, Wu C-J, Hsieh Y-K, *et al*. Percutaneous coronary intervention for iatrogenic left main coronary artery dissection. *Int J Cardiol* 2008;126:177–82.
9 ZHONG HZ, SONG LY, NIE ZY, *et al*. Chocolate balloon (controlled dilatation technique) for vascular preparation of endovascular treatments for lower extremity arteriosclerosis obliterans. *Chin J Interv Imaging Ther* 2024;21.
10 Newman AB, Shemanski L, Manolio TA, *et al*. Ankle-arm index as a predictor of cardiovascular disease and mortality in the Cardiovascular Health Study. The Cardiovascular Health Study Group. *Arterioscler Thromb Vasc Biol* 1999;19:538–45.
11 Diehm C, Schuster A, Allenberg JR, *et al*. High prevalence of peripheral arterial disease and co-morbidity in 6880 primary care patients: cross-sectional study. *Atherosclerosis* 2004;172:95–105.
12 Sampson UKA, Fowkes FGR, McDermott MM, *et al*. Global and Regional Burden of Death and Disability From Peripheral Artery Disease: 21 World Regions, 1990 to 2010. *Gh* 2014;9:145.
13 Fowkes FGR, Rudan D, Rudan I, *et al*. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet* 2013;382:1329–40.
14 Dormandy J, Mahir M, Ascady G, *et al*. Fate of the patient with chronic leg ischaemia. A review article. *J Cardiovasc Surg (Torino)* 1989;30:50–7.
15 McDaniel MD, Cronenwett JL. Basic data related to the natural history of intermittent claudication. *Ann Vasc Surg* 1989;3:273–7.
16 Zeller T. Current state of endovascular treatment of femoro-popliteal artery disease. *Vasc Med* 2007;12:223–34.
17 Lawall H, Huppert P, Espinola-Klein C, *et al*. German guideline on the diagnosis and treatment of peripheral artery disease - a comprehensive update 2016. *Vasa* 2017;46:79–86.
18 Tendera M, Aboyans V, Bartelink M-L, *et al*. ESC Guidelines on the diagnosis and treatment of peripheral artery diseases: Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries: the Task Force on the Diagnosis and Treatment of Peripheral Artery

BMJ Open: first published as 10.1136/bmjopen-2025-103906 on 13 October 2025. Downloaded from http://bmjopen.bmj.com/ on November 18, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Diseases of the European Society of Cardiology (ESC). *Eur Heart J* 2011;32:2851–906.
19 Rook TW, Hirsch AT, Misra S. American College of Cardiology Foundation; American Heart Association; Society for Cardiovascular Angiography and Interventions; Society of Interventional Radiology; Society for Vascular Medicine; Society for Vascular Surgery. 2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery. *Catheter Cardiovasc Interv* 2012;79:501–31.
20 Norgren L, Hiatt WR, Dormandy JA, *et al*. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *Eur J Vasc Endovasc Surg* 2007;33 Suppl 1:S1–75.
21 Yokoi Y. How should recent endovascular trials for femoropopliteal artery disease be interpreted? *Cardiovasc Interv Ther* 2017;32:106–13.
22 Schillinger M, Sabeti S, Loewe C, *et al*. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. *N Engl J Med* 2006;354:1879–88.
23 Dick P, Wallner H, Sabeti S, *et al*. Balloon angioplasty versus stenting with nitinol stents in intermediate length superficial femoral artery lesions. *Catheter Cardiovasc Interv* 2009;74:1090–5.
24 Laird JR, Katzen BT, Scheinert D, *et al*. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. *Circ Cardiovasc Interv* 2010;3:267–76.
25 Hoffmann R, Mintz GS, Popma JJ, *et al*. Treatment of calcified coronary lesions with Palmaz-Schatz stents. An intravascular ultrasound study. *Eur Heart J* 1998;19:1224–31.
26 Fitzgerald PJ, Ports TA, Yock PG. Contribution of localized calcium deposits to dissection after angioplasty. An observational study using intravascular ultrasound. *Circulation* 1992;86:64–70.
27 Rocha-Singh KJ, Zeller T, Jaff MR. Peripheral arterial calcification: prevalence, mechanism, detection, and clinical implications. *Catheter Cardiovasc Interv* 2014;83:E212–20.
28 Allison MA, Criqui MH, Wright CM. Patterns and risk factors for systemic calcified atherosclerosis. *Arterioscler Thromb Vasc Biol* 2004;24:331–6.
29 Kashyap VS, Pavkov ML, Bishop PD, *et al*. Angiography underestimates peripheral atherosclerosis: lumenography revisited. *J Endovasc Ther* 2008;15:117–25.
30 Kawaguchi R, Tsurugaya H, Hoshizaki H, *et al*. Impact of lesion calcification on clinical and angiographic outcome after sirolimus-eluting stent implantation in real-world patients. *Cardiovasc Revasc Med* 2008;9:2–8.
31 Mintz GS, Popma JJ, Pichard AD, *et al*. Patterns of calcification in coronary artery disease. A statistical analysis of intravascular ultrasound and coronary angiography in 1155 lesions. *Circulation* 1995;91:1959–65.
32 Lee MS, Canan T, Rha SW, *et al*. Pooled analysis of the CONFIRM registries: impact of gender on procedure and angiographic outcomes in patients undergoing orbital atherectomy for peripheral artery disease. *J Endovasc Ther* 2015;22:57–62.
33 Babaev A, Zavlunova S, Attubato MJ, *et al*. Orbital Atherectomy Plaque Modification Assessment of the Femoropopliteal Artery Via Intravascular Ultrasound (TRUTH Study). *Vasc Endovascular Surg* 2015;49:188–94.
34 Tepe G, Laird J, Schneider P, *et al*. Drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal peripheral artery disease: 12-month results from the IN.PACT SFA randomized trial. *Circulation* 2015;131:495–502.
35 van Overhagen H, Nakamura M, Geraghty PJ, *et al*. Primary results of the SAVAL randomized trial of a paclitaxel-eluting nitinol stent versus percutaneous transluminal angioplasty in infrapopliteal arteries. *Vasc Med* 2023;28:571–80.
36 Dake MD, Ansel GM, Jaff MR, *et al*. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. *Circ Cardiovasc Interv* 2011;4:495–504.
37 Scheinert D, Scheinert S, Sax J, *et al*. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. *J Am Coll Cardiol* 2005;45:312–5.
38 Sirignano P, Citone M, Menna D, *et al*. Superficial Femoral Artery Stent Disruption Treated by Peripheral Endograft. *Ann Vasc Surg* 2015;29:1661.

BMJ Open: first published as 10.1136/bmjopen-2025-103906 on 13 October 2025. Downloaded from http://bmjopen.bmj.com/ on November 18, 2026 by guest. Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.