


BMJ Open Design of the FP-RESTORE study: a protocol for prospective, observational study of real-world treatments with endovascular therapy in patients with femoropopliteal artery Tosaka III in-stent restenosis

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ABSTRACT

Introduction Femoropopliteal artery in-stent restenosis (FP-ISR) represents one of the main obstacles for stent implantation in peripheral artery disease patients, especially Tosaka III FP-ISR, which is also referred to as in-stent occlusion. Diverse endovascular treatments of Tosaka III FP-ISR are available, and the results are unequivocal. However, real-world data are limited. This study aims to evaluate the efficacy, safety and health economics evaluation of various endovascular procedures in the treatment of Tosaka III FP-ISR.

Method and analysis This study is a prospective, multicentre, real-world, observational clinical study. Patients diagnosed with Tosaka III FP-ISR and treated with endovascular procedures in nine centres from 1 April 2021 to 31 December 2022 will be recruited. The relevant clinical information, Ankle-Brachial Index and CT angiography will be collected. All the participants will undergo follow-up at 1, 6, 12, 18 and 24 months after the operation. The primary outcome is freedom from clinically driven target lesion revascularisation at 24 months. Safety and health economics issues will also be reported.

Ethics and dissemination The FP-RESTORE clinical trial has been registered at ClinicalTrials.gov (<http://clinicaltrials.gov/>). This study was also approved by the Institutional Review Board and Human Research Ethics Committee of Zhongshan Hospital, Fudan University (approval number: B2021-427). Moreover, written informed consent will be obtained at the time of recruitment. The study outcomes will be disseminated by publication in a peer-reviewed journal to provide information for further clinical practice.

Trial registration number NCT04801004.

INTRODUCTION

The femoropopliteal (FP) artery is one of most commonly treated peripheral artery diseases (PAD).¹ The treatment modalities mainly include conservative treatment, endovascular procedures and surgical operations, with

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study is a prospective, multicentre, real-world, observational clinical study.
- ⇒ This study focuses on the efficacy, safety and health economics evaluation of various endovascular operations in the treatment of Tosaka III femoropopliteal artery in-stent restenosis (FP-ISR).
- ⇒ This is an observational study, and no interference with endovascular treatments will occur.
- ⇒ The revascularisation of Tosaka III FP-ISR is associated with poor outcomes.

endovascular treatment being more widely applied. However, FP artery in-stent restenosis (FP-ISR) has become one of the main blocks for stent implantation in PAD patients with high morbidity, especially Tosaka III in-stent restenosis, which is also referred to as in-stent obstruction.²⁻³ Tosaka *et al* reported that the freedom from recurrent ISR at 12 months was 22.7% for Tosaka III lesions compared with 72.5% and 65.6% for Tosaka I and II lesions, respectively.⁴ Armstrong *et al* reported that the freedom from recurrent restenosis at 24 months was 28% for Tosaka III lesions compared with 61% and 34% for TOSAKA I and II lesions, respectively.⁵ This finding indicated that in-stent occlusion correlated with a worse prognosis than in-stent restenosis.

Giannopoulos *et al* reported freedom from target lesion revascularisation (TLR) of 88.9% in the laser debulking devices (LD)+drug coated balloons (DCB) group compared with 54.2% in the LD+ balloon angioplasty (BA) group in a 12-month estimate for the treatment of Tosaka III FP-ISR.⁶ Zhang *et al* reported the results of DCB in the treatment

of Tosaka III FP-ISR with primary patency and freedom from TLR estimates of 79.2% and 91.5%, respectively, at the 14-month follow-up.⁷ Debulking devices (LD or mechanical debulking devices) have also been widely used in the treatment of FP-ISR. Our previous meta-analysis demonstrated that patients with long and occlusive ISR lesions benefit more from debulking devices.⁸ Previous studies have also reported roles for mechanical atherothrombectomy in the treatment of Tosaka III in-stent restenosis with freedom from TLR at 12 months ranging from 43.8% to 84.7%.^{9–12} Given that the outcomes for endovascularly treated Tosaka III FP-ISR varied, there is a need for data from a real-world setting to evaluate the safety, efficacy and economic cost of different endovascular modalities in the treatment of Tosaka III FP-ISR. In a real-world setting, the trial could recruit patients with in-stent occlusion rather than mild in-stent restenosis lesions.

Although there have been clinical reports about the preliminary and midterm stage results of different endovascular treatments in the treatment of Tosaka III FP-ISR patients, these results were still insufficient to reflect real-world clinical practice. Thus, we initiated a clinical trial named the FP-RESTORE study to examine the safety, effectiveness and economic cost of different endovascular therapies in the treatment of Tosaka III FP-ISR patients in a real-world setting across China.

METHODS

Study design

FP-RESTORE is a prospective, multicentre, real-world, observational clinical study that aims to evaluate the safety, efficacy and economic cost of different endovascular therapies in Tosaka III (totally occluded) in-stent restenosis. It is estimated that 300 subjects diagnosed with FP artery Tosaka III in-stent restenosis and receiving endovascular treatments will be enrolled in nine centres from April 2021 to December 2022 nationwide in China. No restrictions on the endovascular techniques used will be employed to make it easier to compare the effects of different endovascular treatments in Tosaka III in-stent restenosis.

The main purpose is to observe the freedom from clinically driven TLR (CD-TLR), primary patency, the improvement in quality-of-life score and health economics evaluation.

The study was designed and initiated by the Department of Vascular Surgery, Zhongshan Hospital, Fudan University. No patient or public involvement is required.

Participants

To minimise bias in the selection of patients, investigators at participating sites are encouraged to recruit all eligible Tosaka III in-stent restenosis patients receiving endovascular treatments. The patients will be screened for enrolment from April 2021 to December 2022 in nine designated centres across China. A total of 300 patients

who received stent implantation to treat PAD and developed Tosaka III FP-ISR will be recruited. Recruitment is non-competitive and will not affect clinical practice.

Criteria

Inclusion criteria

1. Tosaka III In-stent restenosis after stent implantation in PAD patients (Including acute and subacute thrombotic lesions).
2. Rutherford grade 2–5.
3. Stents should be located in the FP artery.
4. The stenosis of iliac artery on the affected side is less than 30% or the residual stenosis after treatment is less than 30%.
5. Informed consent has been signed.

Exclusion criteria

1. Tosaka I or II in-stent restenosis.
2. Stents are located in iliac artery or artery below the knee, or the preoperative CTA showed type 3 or 4 stent fracture.
3. Rutherford grade 6.
4. Thromboangiitis obliterans-based, arteritis-based or connective tissue disorder-based FP-ISR.
5. Intraoperative conversion to hybrid or open surgery.
6. Patients refusing to sign informed consent forms.
7. Life expectancy of patients is less than 12 months.
8. The pregnant or nursing patients.
9. The patients with severe ischaemia of lower extremity who would receive major amputation in plan.
10. Patients in whom antiplatelet or anticoagulant therapy is contraindicated.
11. Myocardial infarction or stroke within 3 months prior to enrolment.
12. Patient with known allergy to contrast agents or medications used to perform endovascular intervention.
13. Patients participating in another research study involving an investigational agent (pharmaceutical, biologic or medical device) that has not reached the primary endpoint.
14. Patients who refuse to cooperate with long-term follow-up or who have difficulty communicating.

Criteria for discontinuing

Subjects could discontinue participation in this trial at any time for any reason without any consequences. In addition, the investigators could decide whether the patient is excluded from the study depending on the following conditions.

1. The patients are lost to follow-up.
2. The patients voluntarily withdraw their informed consent.
3. In case of serious violation of the study protocol by investigators or subjects.
4. Patient is simultaneously participating in another investigational drug or device study.
5. Patient has any planned surgical or interventional procedure within 30 days after the study procedure.

Once the subject discontinued participation in the trial, his or her relevant primary outcomes and secondary outcomes would be eliminated.

Endovascular procedure

All enrolled patients will be treated with endovascular therapies. In general, endovascular approaches are established from the contralateral common femoral artery or the ipsilateral common femoral artery or a brachial approach. Retrograde puncture access via the popliteal artery will be chosen once intervention with the antegrade approach is unsuccessful. Angiography will be performed to assess the lesion severity, length and location. Then, angiography of the target artery will be performed, and the guide wire will be passed through the in-stent occlusion lesion. Then, multiple types of endovascular treatments, including BA, DCB, drug eluting stent implantation, bare metal stent (BMS) implantation, intravascular lithotripsy, directional atherectomy, LD, stent-graft implantation or a combination of the above, will be applied according to the characteristics of the lesion and physician preferences. Generally, BA and DCB will be used as the basis for endovascular treatment of FR-ISR. Thrombectomy devices will be applied in acute or subacute thrombosis lesions, and both LD devices and atherectomy debulking devices are preferred in chronic long lesions. The devices used intraoperatively will be based on the operator's preferences. Final angiography will be performed to assess the efficacy of endovascular treatment. Residual stenosis of less than 30% will be defined as technical success.

Recruitment

All suitable patients will receive a routine examination during admission. Patients will receive intraoperative angiography of lower extremity artery, and data on the lesion length, stenosis degree, extent of lesion, collateral circulation will be assessed. Moreover, eligible patients will be enrolled after signing the informed consent form.

Data collection

A standard case report form (CRF) has been established at the beginning of this study. This CRF will collect the patients' quality of life (QoL), systemic disease history, perioperative risk factor assessment, clinical symptom classification, lesion location and Trans-Atlantic Inter-Society Consensus II classification, endovascular procedure details, treatment outcomes and complications as well as follow-up information. Two investigators will perform the data input independently, and data input verification will be conducted to reduce the chance of error. The original CRF will be archived by the sponsor, and a copy of the CRF will be kept at the centre and transferred into electronic records in a correlated data management system. This system covers preoperative assessment, intraoperative details and follow-up information.

Surveillance and follow-up

Follow-up will be coordinated by each participating centre independently. The follow-up information will be

obtained via telephone interviews and outpatient clinical visits. To improve the shortcoming of the detail of reintervention cannot be acquired in telephone follow-up, we would encourage the participants to provide the medical records of reintervention detail and conduct the outpatient visit immediately if he received reintervention during follow-up period. The telephone interview follow-up information includes ambulation improvements, current medication, smoking status, wound healing (if necessary), rehospitalisation and QoL. Outpatient clinical visit follow-up information includes ABI, Rutherford classification, vascular ultrasound, the need for reintervention and the presence of new-onset lesions.

These relevant details will also be recorded in the CRF and transferred into electronic records in the lower extremity artery data management system. All centres participating in this study will have access to the data. The participant's personal information will be encrypted to prevent leakage. All the participants will undergo follow-up at 1, 6, 12, 18 and 24 months after the operation.

Outcome measures

The primary outcome of the study is freedom from CD-TLR at 24 months. CD-TLR is defined as any reintervention within the target lesion(s) because of recurrent symptoms. Freedom from CD-TLR is defined as the rate of the number of patients who did not receive reintervention versus the number of patients during the follow-up period.^{13 14} The secondary outcomes include (1) primary patency, which was defined as the percentage of stent patency examined by DUS or CTA examination during follow-up; (2) technical success rate; (3) incidence of major adverse events; (4) freedom from CD-TLR at 1, 6, 12 and 18 months; (5) assessment using The Vascular Quality of Life Questionnaire, which contains five domains to evaluate health-related QoL, including pain (four items), symptoms (four items), activities (eight items), social (two items) and emotional (seven items) and (6) health economics evaluation, which is defined as all the costs related to the target vessel revascularisation in the inpatient ward. Moreover, the health economics evaluation of technique failed participants will also be included.

Adverse events

The adverse events will be categorised into minor and major adverse events, and the frequency of minor and major adverse events during the treatment period and follow-up period will both be recorded. The minor adverse events included arterial puncture complications, distal embolism without clinical manifestations, postoperative thrombosis without critical limb ischaemia and reversible contrast induced nephropathy. In addition, major adverse events include major amputation related to endovascular treatment, cardiovascular and cerebrovascular events, arterial puncture complications requiring intervention, progressive haemoglobin disease, acute renal failure and death. Once adverse events are

identified, the corresponding centres will actively manage and report the adverse events. The adverse events and the process of treatment will be documented and reported to the corresponding ethics committee. Once death events occur, the corresponding centres and the participating investigator should immediately provide all necessary information to the ethics committee.

Sample size and statistical analysis

Taking into account a 10% lost to follow-up rate and a target enrolment of 300 patients, 270 patients will be included in the effectiveness analysis.

Statistical analysis will be performed using Stata SE V.15.1 software (StataCorp). Continuous data will be presented as the mean±SD, and categorical data will be presented as numbers (n) and percentages (%). Normal distribution and homogeneous tests of variance will be performed in advance. For the data groups that have a normal distribution and homogeneous variances, comparisons between two groups will be made using unpaired Student's t-tests and one-way analysis of variance, followed by Bonferroni tests for multiple group comparisons. For the data groups that do not have a normal distribution or homogeneous variances, nonparametric tests will be used. Univariate and multivariate analyses will be performed by logistic analysis. Generally, a two-sided $p < 0.05$ will be considered statistically significant unless otherwise stated.

Patient and public involvement

Patients or the public will not be involved in the design, or conduct, or reporting, or dissemination plans of our research.

DISCUSSION

The FP-RESTORE will be the first study to provide prospective data on the effectiveness, safety and health economics evaluation of different endovascular modalities in the treatment of Tosaka III FP-ISR in a real-world setting. The endovascular treatments employed in FP-ISR include BA alone, DCB, cutting balloon, BMS, covered stent, mechanical debulking devices, laser atherectomy or a combination of the above.^{13–25} However, the methods and results widely vary, which makes it difficult to compare the outcomes and make valid conclusions. FP-RESTORE is thus designed to evaluate and compare these endovascular procedures for Tosaka III FP-ISR. We hope our results will provide useful information and guidance about this issue and references for future controlled studies.

CD freedom from TLR is the primary outcome in our study. On the one hand, FP-RESTORE is designed to pay more attention to the clinical efficacy of various endovascular modalities; thus, CD freedom from TLR could reflect the clinical effectiveness more intuitively. On the other hand, the inclusion criteria in real-world settings are not as strict as those of controlled studies; thus, a broader range of patients could be enrolled. Given that

the patients are recruited throughout China, the imaging follow-up rate at different centres will vary widely, which may lead to missing information regarding primary patency. Thus, CD freedom from TLR will serve as the primary outcome, whereas primary patency and other results will serve as secondary outcomes in this study.

The patient's enrolment started at 1 April 2021 actually. The inclusion criteria 'The length of occluded lesion is ≥ 5 cm'. and the exclusion criteria 'or stent occlusion lesion less than 5 cm in length' has been deleted in 13 August 2022 to keep consistent with Tosaka classifications. Since this study was a real-world setting observational study, we discussed with the statistician in our group and concluded the modification of inclusion and exclusion was acceptable in post hoc adaptation period.

Ethics and Dissemination

The FP-RESTORE clinical trial has been registered in ClinicalTrials (<http://clinicaltrials.gov/>). This study has also been approved by the Institutional review board and Human Research Ethics Committee of Zhongshan hospital, Fudan university (Approved number: B2021-427). Moreover, the written informed consent will be obtained at the time of recruitment. The trial protocol complies with the Declaration of Helsinki. The study outcomes will be disseminated by publication in a peer-reviewed journal. The relevant confidential information will be transferred into a specific code to avoid potential leakage. In addition, the trial design has also been registered at ClinicalTrials.gov (Number: NCT04801004).

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Contributors The authors have been included in this manuscript based on the ICMJE recommendations. XL, MZ, YD and ZS planned and designed the study. MY and ZW reviewed the structure of this manuscript. XL, MY, ZW, ZF, LG, QL, XF and HS contributed to patient enrolments and collection of patient data. ZS critically reviewed and approved this manuscript. All authors have read and approved the final manuscript.

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Competing interests None declared.

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