Journal of Cardiothoracic Surgery

RESEARCH

Open Access

Rotarex®S rotational atherectomy combined with drug-coated balloon angioplasty for treating femoropopliteal artery in-stent restenosis

Hui Wang[1†], Sensen Wu[1†], Wenzhuo Meng[1], Dikang Pan[1], Yachan Ning[1], Jianming Guo[1*], Lianrui Guo[1] and Yongquan Gu[1*]

Abstract

Objective This study aimed to analyze the safety and mid-term outcomes of a hybrid treatment method combining rotational atherectomy (RA) with drug-coated balloon (DCB) angioplasty in patients with femoropopliteal artery in-stent restenosis (ISR).

Methods This single-center retrospective study enrolled patients from January 2018 to March 2022 who had femoropopliteal artery in-stent restenosis treated by RA and DCB. Preoperative demographics, operative details, and postoperative 12-month follow-up outcomes were analyzed statistically.

Results 38 consecutive patients (31 men; mean age 69.55 ± 9.18 years, range 54–91 years) with Tosaka II ($n = 8$) and III ($n = 30$) ISR were treated with RA Most patients had a high prevalence of typical vascular comorbidities. Overall, 50% of patients had chronic limb-threatening ischemia, and the average lesion length was 155.0 ± 54.8 mm. The primary patency rate, assessed by duplex ultrasound at 12 months, was 86.7%; 7.9% (3/38) of patients underwent target lesion revascularization (TLR). The overall mortality rate was 2.6% (1/38), and the ulcer healing rate reached 83.3% (5/6), with none of these patients requiring amputation. Subgroup analysis based on target lesion length (≥ 200 mm) showed that the 12-month primary patency rate was 75.0% for the ≥ 200 mm group and 95.5% for the < 200 mm group. Cox univariate regression analysis did not identify any risk factors affecting primary patency rate and freedom from clinically driven TLR (CD-TLR) at 12 months.

Conclusions Rotarex®S combined with DCB seems safe and provides acceptable 12-month primary patency and TLR rates in femoropopliteal in-stent restenosis. Well-designed comparative or large registry studies are necessary to

†Hui Wang and Sensen Wu contributed equally to the article and shared the first author. Yongquan Gu and Jianming Guo are listed as co-corresponding authors of this article.

*Correspondence:
Jianming Guo
jianmingguoxuanwu@163.com
Yongquan Gu
gu15901598209@aliyun.com

Full list of author information is available at the end of the article

provide high quality and long-term data on this technique to provide firm conclusions on the efficacy of Rotarex®S and DCB in ISR in the femoropopliteal area.

Keywords Rotational atherectomy (RA), Drug-coated balloon (DCB), Femoropopliteal artery, In-stent restenosis (ISR), Angioplasty

Introduction

Due to its low level of invasiveness, few complications, and replicable treatments, endovascular therapy is presently acknowledged as an effective treatment for peripheral artery disease (PAD), especially plain old balloon angioplasty (POBA), bare metal stent and so on [1]. Therefore, lots of stents are implanted in the femoropopliteal artery to treat primary lower extremity arterial ischemia; however, due to the unique anatomical location, strong proliferation ability of smooth muscle cells, complex mechanical forces imposed on these vessels, stent fracture, and other reasons, it's easily lead to femoropopliteal artery in-stent restenosis (FP-ISR) [2–5]. According to reports, FP-ISR incidence ranged from 19 to 27% at 12 months to approximately 50% at 24 months and up to 60% at 36 months [6–8].

In recent years, various endovascular treatments have been applied to FP-ISR, and many studies have shown that DCB is significantly more effective than POBA; primary patency can be maintained at 70.3-92.1% at 12 months [9–11]. However, for complex long-segment lesions, the ability to sustain primary patency over the long term has been viewed as a limitation of DCB angioplasty [12, 13]. Recent researches on the treatment of FP-ISR is beginning to investigate the role of DCB in conjunction with debulking devices, such as laser, directional atherectomy (DA), orbital atherectomy, and RA [14]. There are few reports on using RA+DCB for FP-ISR in China, so this study focuses on analyzing the mid-term outcomes and safety of RA+DCB.

Materials and methods

Study design and patient population

This is a retrospective study of FP-ISR patients treated with Rotarex®S (Straub Medical AG, Wangs, Switzerland) at our center from January 2018 to March 2022. We identified 38 consecutive patients who met the inclusion criteria. Patient selection is based on the clinical team's experience at our center and is determined through comprehensive discussion among seven chief physicians. Patients selected primarily include those with in-stent thrombosis and hyperplastic intima, while patients with calcified lesions are excluded. The ethical review of the study was approved by our center's ethical review board with the ethical approval number [2022] 054, and all patients signed an informed consent form prior to treatment, as the study was a retrospective study clinical trial number was not applicable.

Procedure

All patients received dual antiplatelet therapy (100 mg/d aspirin and 75 mg/d clopidogrel) at the time of the procedure. A device used in this study was the Rotarex®S System, with 6-, 8-French (Fr) sheath-compatible devices, depending on the vessel diameter to be treated. One attending physician team in the endovascular suite performed the procedures using a fixed image intensifier (AX axiom Artis dTA, 55094, Siemens, Germany).

Patients underwent endovascular treatment with local anesthesia; access was established by anterograde puncture in the ipsilateral femoral artery or retrograde puncture in the contralateral femoral artery after intravenous heparin administration (50–70U/kg) and diagnostic angiography. When the catheter reaches the target limb, a femoral artery angiogram is performed to clarify the extent, scope, and diameter of the lesion. Then, attempt to use hydrophilic coated guide wire (Boston Scientific, Natick, MA, United States) passed the lesion segment. After reaching the distal true lumen, change the special 0.018-inch wire to match the Rotarex®S system.

During operation, make the Rotarex®S system advance along the guide wire at a speed of 0.5 cm/s. When an occlusion is met, the rotating head breaks down the occlusive material. A second angioplasty was performed with a paclitaxel-coated balloon (Orchid, Acotec Scientific Co.Ltd.), and DCB inflation was approximately 3 min. If>30% residual stenosis and flow-limiting dissection were present, a bailout stent (Medtronic, Bard, or Biotronik) was implanted. The procedure was regarded as successful when residual stenosis<30%.

Follow-up

Dual antiplatelet therapy will be continued for at least six months after discharge from the hospital; all patients underwent surveillance by lower limb duplex ultrasonography by the following schedule: 3rd month, 6th month, and 12th month.

Definitions and study endpoint

Assessment of FP-ISR stenosis using the TOSAKA classification [15]. Class I ISR (focal, ≤50 mm in length) included lesions in the stent body, at the stent edge, or a combination of these sites. Class II refers to diffuse (>50 mm long) ISR lesions in the stent body or at the stent edges. Class III was an occluded stent.

The primary patency at 12-month follow-up was the primary endpoint in this study(primary patency

was defined as a<50% diameter reduction based on duplex criteria of a proximal systolic peak flow velocity ratio > 2.4). Secondary endpoints were technical success (technical success was defined as successful lesion crossing and final residual stenosis < 30% for a treated lesion.), freedom from CD-TLR at 12-months, clinical success (improvement in clinical Rutherford-Becker category at 3-, 6- and 12-months after operation). Safety endpoints included all-cause death, unplanned major amputation, and adverse events (flow-limiting dissection, hematoma, perforation, urgent target lesion thrombolysis). Subgroup analyses were performed for lesions greater than 200 mm and less than 200 mm in length to explore whether there were differences when treating different lengths in this manner.

Statistical analysis

Data are expressed as proportions for dichotomous variables and as the mean ± SD or median and interquartile range (IQR) for continuous variables. The Kaplan- Meier method estimated freedom from CD-TLR and primary patency rates. An exploratory COX univariate regression analysis was performed to identify predictors of any recurring restenosis. Known predictors (including lesion length, Tosaka class III restenosis pattern, bailout stent, plus age and gender as background variables) were included. A probability value of $p<0.05$ was considered statistically significant. All analyses were performed using SPSS 27.0 software (SPSS Inc., Chicago, IL, United States). The figures in this paper were made by GraphPad Prism 9.4.1(GraphPad Software, LLC.).

Results

This is a single-center retrospective observational study of 38 patients (31 men; mean age 69.55 ± 9.18 years, range 54–91 years) with FP-ISR treated with RA from January 2018 to July 2022. Most patients with a high prevalence of typical vascular comorbidities, including diabetes mellitus (68.4%), hypertension (76.3%), hyperlipidemia (65.8%), coronary artery disease (42.1%), cerebrovascular disease (21.1%), smoking history (42.1%). A significant proportion of ISR patients received guideline-directed medical therapy (antiplatelet, statin). The mean ABI was 0.79 ± 0.23 before the operation. Half of the patients in our trial had a Rutherford grade of 4–5 (Table 1).

The average lesion length of the target lesion was 155.0 ± 54.8 mm, with superficial femoral artery (SFA) alone (60.5%) and SFA + popliteal artery (PA) (39.5%) vessel segments as the most treated. Among them, early ISR patients account for 24.7%, while late ISR patients account for 76.3%. During the procedure, overall procedure success was achieved in 38 (100%) patients; 3 patients used a filter, flow-limiting dissection occurred in 4 patients, one had subcutaneous hematoma, and there were ten bailout stent implantations (Table 2).

All these patients had a follow-up time of over 12 months. The primary patency rate was 84.1%, and the freedom from CD-TLR rate was 92.1% at 12 months

Table 1 Patient demographics and clinical characteristics of 38 patients in the study

Characteristic	Values(*N* = 38)
Age (years)	69.55 ± 9.18
Gender	
Male	31(81.6%)
Female	7(18.4%)
Comorbidities	
Diabetes mellitus	26(68.4%)
Hypertension	29(76.3%)
Hyperlipidemia	25(65.8%)
Coronary artery disease	16(42.1%)
Cerebrovascular disease	8(21.1%)
Smoking history	16(42.1%)
Chronic kidney disease	1(2.6%)
Aspirin	25(65.8%)
Clopidogrel	17(44.7%)
Statin	32(84.2%)
ABI	0.41 ± 0.18
Rutherford classification	
Class 2	2(5.3%)
Class 3	17(44.7%)
Class 4	13(34.2%)
Class 5	6(15.8%)

ABI: ankle brachial index

Continuous data are presented as the mean ± standard deviation; categorical data are given as the number (percentage)

Table 2 Angiographic and procedural characteristics

Variables	Values
Vessels involved	
SFA	23(60.5%)
PA	0(0%)
SFA + PA	15(39.5%)
Average lesion length, mm	155.0 ± 54.8
Tosaka classification	
Tosaka I	0(0%)
Tosaka II	8(21.1%)
Tosaka III	30(78.9%)
ISR classification	
early ISR	9(24.7%)
late ISR	29(76.3%)
Approach	
Ipsilateral	7(18.4%)
Contralateral	31(81.6%)
Technical success	38(100%)
Filter used	3(7.9%)
Bailout stenting	10(26.3%)
Embolization	6(15.8%)
Thrombolysis	0(0%)
Dissection (Flow-limiting)	4(10.5%)
Hematoma	1(2.6%)
Perforation	0(0%)

PA: popliteal artery; SFA: superficial femoral artery, ISR: in-stent restenosis

Continuous data are presented as the mean ± standard deviation; categorical data are given as the number (percentage)

Table 3 12 Months outcome for femoropopliteal in-stent restenosis treated with rotational atherectomy

Variables	Values
Primary patency at 12 months	32/38(84.1%)
Freedom from CD-TLR at 12 months	35/38(92.1%)
Healing at 12 months	5/6 (83.3%)
ABI (post operation)	0.79 ± 0.23
Major amputation	0/38(0%)
Death	1/38(2.6%)

CD-TLR: clinically driven target lesion revascularization, ABI: Ankle–brachial index, Categorical data are given as the counts (percentage), Continuous data are presented as the mean ± standard deviation

(Table 3; Fig. 1). Overall mortality was 2.6% (1/38); one patient died of coronary artery disease 11 months after surgery, the ulcer healing rate reached 83.3% (5/6), and none of these patients needed amputation (Table 3). The mean ankle-brachial index (ABI) was 0.83 ± 0.13 before discharge; the change in the Rutherford category at 3-, 6-, and 12-month follow-up is presented in Fig. 2.

To further investigate RA's therapeutic efficacy for patients with different characteristics of FP-ISR, a subgroup analysis was performed based on a target lesion length of ≥200 mm. Comparing the lesion length ≥ 200 mm group and < 200 mm group, the 12-month primary patency was 75.0% and 95.5%; the freedom from CD-TLR at 12 months was 87.5% and 95.5%, respectively (Fig. 3). Subgroup analysis was not performed according to ISR classification because most patients were TOSAKA III. COX univariate regression analysis didn't find risk factors affecting the primary patency and freedom from CD-TLR (supplement material).

Discussion

Our study demonstrates that using RA and DCB for treating FP-ISR lesions during the perioperative period is associated with higher safety. All patients underwent successful surgery without any adverse events, and all patients were limb-salvage. Only one patient died due to coronary artery disease. During the 1-year follow-up period, there was a higher initial patency rate and freedom from clinically driven target lesion revascularization. Subgroup analysis based on lesions ≤ 200 mm did

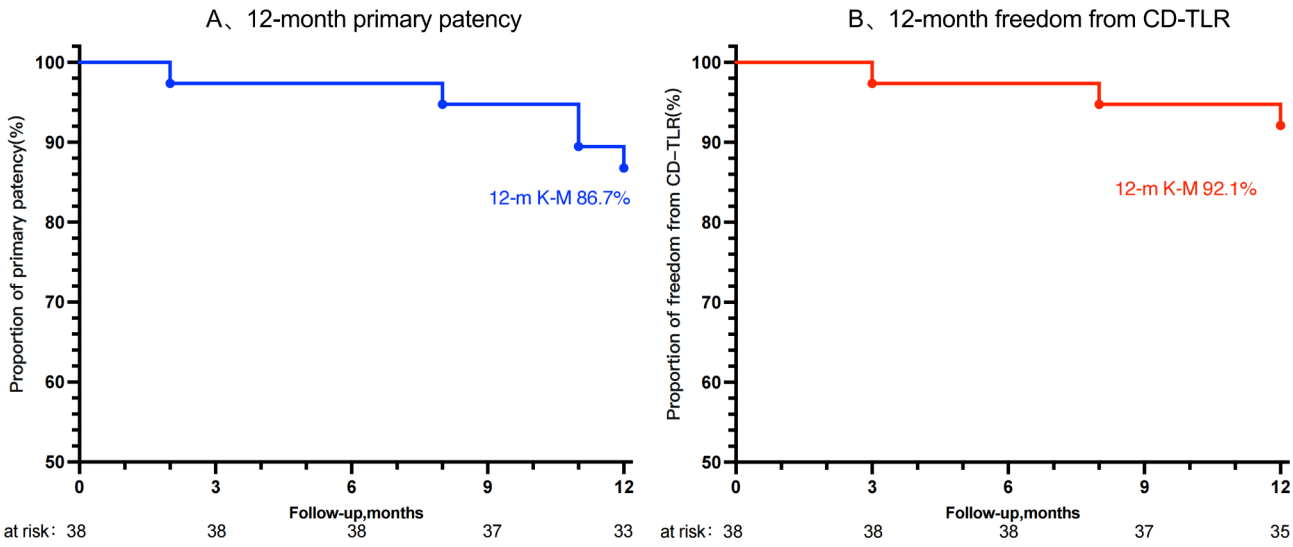

Fig. 1 Kaplan–Meier survival curves showing 12-month (**A**) primary patency rate and (**B**) freedom from target lesion revascularization (TLR)

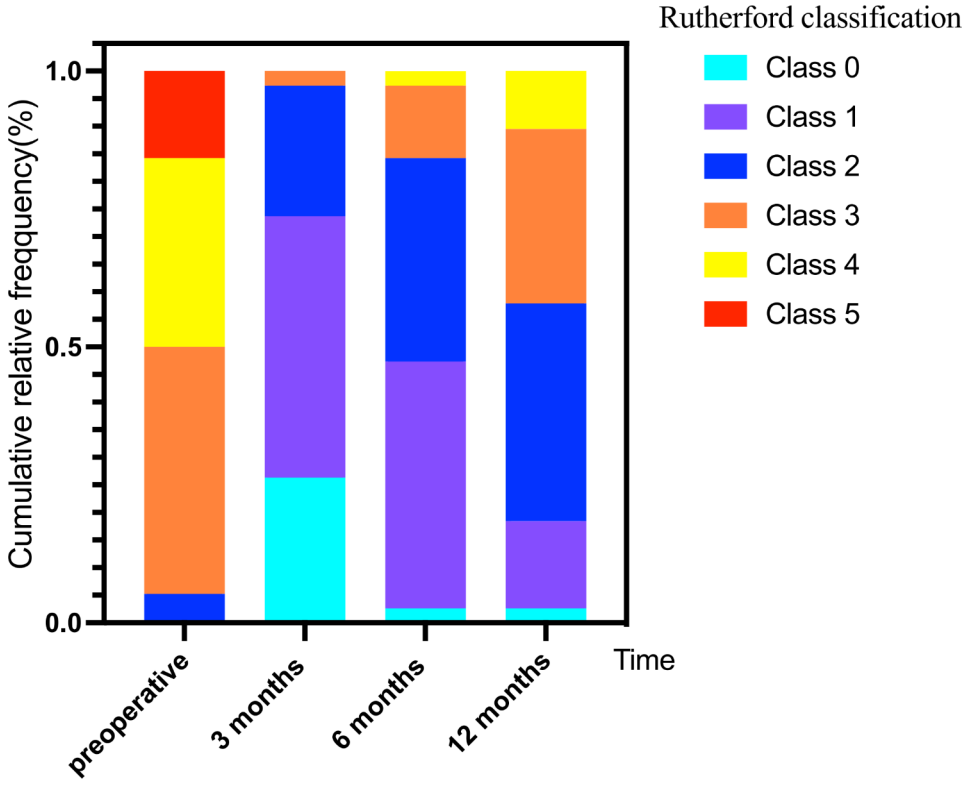

Fig. 2 The change in Rutherford category at 3-, 6-, 12-month follow-up

not reveal statistically significant differences in primary patency or CD-TLR between the two groups.

The mechanisms of FP-ISR are complex and include progression of atherosclerosis, inadequate postoperative anticoagulation therapy, and continuous intimal compression resulting in smooth muscle cell migration and proliferation, as well as massive extracellular matrix formation and release of various inflammatory cytokines; FP-ISR can be caused by any of these factors [16, 17]. In the early stage, ISR is mainly caused by platelet aggregation and thrombosis due to endothelial injury. Late ISR is primarily due to an inflammatory response induced by long-term stimulation of the endothelium by the stent. This results in smooth muscle cell proliferation, extracellular matrix formation, and a reduction in luminal diameter [18, 19].

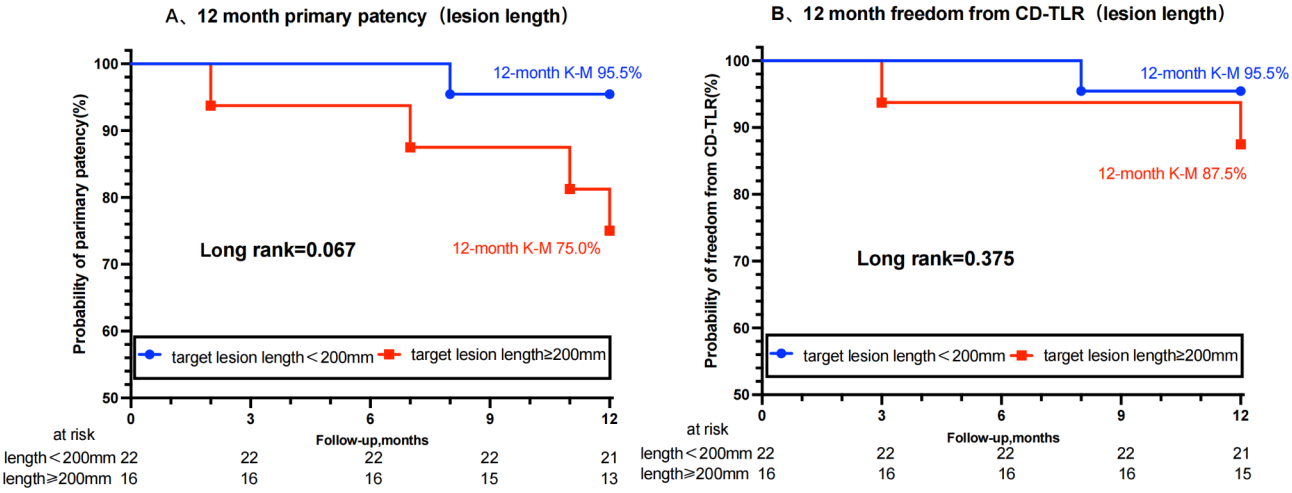

Fig. 3 Kaplan–Meier survival curves for subgroup analysis 12-month (**A**) primary patency rate and (**B**) freedom from target lesion revascularization (TLR)

To effectively solve the problem of FP-ISR, many scholars have proposed and studied various methods for treating ISR, such as POBA, bare metal stent, cutting balloon, DCB, drug-eluting stent, resorbable scaffolds, etc. POBA is the oldest treatment for FP-ISR; however, the midterm and long-term results were disappointing [13, 20]. Tosaka et al. [15] retrospectively analyzed 133 cases of FP-ISR; the recurrent ISR rate was 49.9% in Class I, 53.3% in Class II, and 84.8% in Class III after POBA treatment at two years. Repeat bare metal stent implantation is not recommended because it can further stimulate the inflammatory response, leading to recurrent stenosis [6, 21, 22].

Because intimal hyperplasia is the main contributor to ISR, which differs from de novo atherosclerotic lesions, in recent years, DCB has been widely used in the FP-ISR. When the DCB is inflated, the antiproliferative drug is released into the vessel wall, inhibiting intimal hyperplasia and inflammation caused by local vascular injury; some studies showed that DCB is advantageous in reducing TLR and recurrent ISR [11, 23]. However, debulking combined with DCB appears to provide more definitive efficacy for long-segment complex lesions. Endovascular debulking devices could be divided into four categories: directional, rotational, orbital, and laser atherectomy [24]. This paper conducted a 1-year follow-up study on FP-ISR patients receiving RA treatment, which proved the effectiveness and safety of RA.

The Straub Rotarex®S catheter tip comprises two overlying metal cylinders with two side openings. The inner cylinder is connected to the catheter shaft, and the outer cylinder is connected to the rotating helix. The outer cylinder is fitted with facets at its foremost head, which, when working, abrade thrombotic material lying in front of it. The helix and the catheter tip rotate at 40,000–60,000 rpm; when a thrombotic occlusion is met, the rotating head breaks down the material with its small, blunt facets in its forward aspect. At the same time, the rotation of the catheter tip creates a vortex effect in the circulation, which helps to erode occlusive material from the vessel lumen [25–27] further.

Due to its unique working method, the Rotarex®S device not only can remove thrombi and emboli from the peripheral arterial system without thrombolytics used in the treatment of acute mesenteric ischemia or acute limb ischemia but also is a purely mechanical endovascular atherectomy [28–30]. Liao et al. [31] reported on RA angioplasty in 32 patients with FP-ISR at 12-month follow-up, primary patency (86.2%), and freedom from TLR (89.7%), consistent with our study's results. According to retrospective multicenter research, the primary clinical success/patency rate for the Rotarex®S device in peripheral artery ISR was 92.3% at 12-month follow-up, and the TLR rate was 19.5% [32].

Clinically, the distinction between long and short lesions is typically made at 150–200 mm. To investigate whether there is any significant difference between long and short lesions when treated with RA, a subgroup analysis was carried out in this research using 200 as the border. There was no statistically significant difference because both groups used the RA method. However, some studies have indicated that Debulking may offer a statistically meaningful benefit for long-segment complicated FP-ISR lesions [33, 34].

Although many studies have confirmed the safety and efficacy of RA, the following points should be noted during operation: First, to prevent incomplete aspiration caused by the head end of the aspiration catheter being advanced too quickly and the embolus being rushed to the distal end by the blood flow, which may result in a distal artery embolism, it is advised to first slowly advance the aspiration catheter from the proximal end to the distal end. Second, halt the procedure immediately if

you hear anything unusual during the operation to prevent damaging the stent or vessel wall, then remove the catheter for flushing to ensure safety. Finally, a filter may be considered to lessen the likelihood of embolic complications when patients only have one outflow pathway below the knee.

Limitation

Our study has several limitations inherent to its design. First, selection bias may have influenced the results due to the study's retrospective nature and single-center design. The patient cohort was limited to those treated at a single institution, which may not fully represent the broader population of patients with femoropopliteal in-stent restenosis (FP-ISR). Second, the sample size of 38 patients may have limited the statistical power to detect smaller, yet clinically relevant differences. This could lead to type II statistical errors. Third, the study's generalizability is restricted by its single-center setting and the specific demographic and clinical characteristics of the patient population, which included a predominance of older male patients with multiple vascular comorbidities. Therefore, caution should be exercised when applying these findings to populations with different demographic profiles or healthcare settings. Additionally, scientific and clinical evidence suggests that IVUS is highly beneficial for complete control of intravascular revascularization. However, due to reasons such as availability, we did not perform IVUS on the patients. Instead, we have used DSA from various angles to comprehensively assess the results of vascular reconstruction. Despite these limitations, the study provides valuable insights into the outcomes of rotational atherectomy in treating FP-ISR. Future research with larger, multicenter cohorts and diverse patient populations could further elucidate the effectiveness and generalizability of these findings.

Conclusions

Rotarex®S combined with DCB seems safe and provides acceptable 12-month primary patency and TLR rates in femoropopliteal in-stent restenosis. Well-designed comparative or large registry studies are necessary to provide high quality and long-term data on this technique to provide firm conclusions on the efficacy of Rotarex®S and DCB in ISR in the femoropopliteal area.

Acknowledgements
We thank the authors and participants of the included studies for their vital contributions.

Author contributions
H.W. and S.W. initially conceptualized and designed the project; W.M., D. P. and H.W. were major contributors to data collection and the writing of the manuscript; Y.N., J.G., L.G.and Y.Q. participated in data interpretation and contributed to the writing of the manuscript. All authors have read and approved the final manuscript.

Funding
This research was funded by the National Key Research and Development Program of China (2021YFC2500500) and Beijing Municipal Science & Technology Commission (No. Z241100009024028)

Data availability
No datasets were generated or analysed during the current study.

Declarations

Competing interests
The authors declare no competing interests.

Ethical approval number
[2022] 054.

Clinical trial number
Because this was a retrospective study clinical trial numbers were not applicable.

Author details
[1]Department of Vascular Surgery, Xuanwu Hospital, Capital Medical University, No. 45, Changchun Street, Beijing 100053, China

Received: 2 July 2024 / Accepted: 1 December 2024
Published online: 19 December 2024

References

1. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the management of patients with lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice guidelines. Circulation. 2017;135(12):e726–79.
2. Montelione N, Catanese V, Nenna A et al. The diagnostic value of circulating biomarkers and role of drug-coated balloons for In-Stent restenosis in patients with peripheral arterial disease. Diagnostics (Basel). 2022;12(9).
3. Doshi R, Kumar A, Adalja D, et al. Meta-analysis of usefulness of Drug Coated Balloon Versus Standard Balloon in the treatment of Femoropopliteal In-Stent-Restenosis. Am J Cardiol. 2020;133:170–1.
4. Kayssi A, Al-Jundi W, Papia G, et al. Drug-eluting balloon angioplasty versus uncoated balloon angioplasty for the treatment of in-stent restenosis of the femoropopliteal arteries. Cochrane Database Syst Rev. 2019;1(1):Cd012510.
5. Nakabayashi K, Hata S, Kaneko N, et al. Pseudo-aneurysm caused by stent fracture in the sub-acute phase after endovascular therapy for in-stent restenosis lesions. J Cardiol Cases. 2020;22(1):11–4.
6. Singh GD, Armstrong EJ, Laird JR. Femoropopliteal in-stent restenosis: current treatment strategies. J Cardiovasc Surg (Torino). 2014;55(3):325–33.
7. Kokkinidis DG, Behan S, Jawaid O, et al. Laser atherectomy and drug-coated balloons for the treatment of femoropopliteal in-stent restenosis: 2-Year outcomes. Catheter Cardiovasc Interv. 2020;95(3):439–46.
8. 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(3):267–76.
9. Stabile E, Virga V, Salemme L, et al. Drug-eluting balloon for treatment of superficial femoral artery in-stent restenosis. J Am Coll Cardiol. 2012;60(18):1739–42.
10. Virga V, Stabile E, Biamino G, et al. Drug-eluting balloons for the treatment of the superficial femoral artery in-stent restenosis: 2-year follow-up. JACC Cardiovasc Interv. 2014;7(4):411–5.
11. Brodmann M, Keirse K, Scheinert D, et al. Drug-coated balloon treatment for Femoropopliteal Artery Disease: the IN.PACT Global Study De Novo In-Stent Restenosis Imaging Cohort. JACC Cardiovasc Interv. 2017;10(20):2113–23.
12. Liistro F, Angioli P, Porto I, et al. Paclitaxel-eluting balloon vs. standard angioplasty to reduce recurrent restenosis in diabetic patients with in-stent restenosis of the superficial femoral and proximal popliteal arteries: the DEBATE-ISR study. J Endovasc Ther. 2014;21(1):1–8.
13. Kinstner CM, Lammer J, Willfort-Ehringer A, et al. Paclitaxel-Eluting Balloon Versus Standard Balloon Angioplasty in In-Stent restenosis of the superficial

femoral and proximal popliteal artery: 1-Year results of the PACUBA Trial. JACC Cardiovasc Interv. 2016;9(13):1386–92.
14. Varela DL, Armstrong EJ. Endovascular Management of Femoropopliteal In-Stent restenosis: a systematic review. Cardiovasc Revasc Med. 2019;20(10):915–25.
15. Tosaka A, Soga Y, Iida O, et al. Classification and clinical impact of restenosis after femoropopliteal stenting. J Am Coll Cardiol. 2012;59(1):16–23.
16. Krishnan P, Tarricone A. Intravascular ultrasound guided directional atherectomy versus directional atherectomy guided by angiography for the treatment of femoropopliteal in-stent restenosis. Ther Adv Cardiovasc Dis. 2018;12(1):17–22.
17. Srimurugan B, Sigler M, Sankar NM, et al. In-stent restenosis: surgical and histopathological perspective. Asian Cardiovasc Thorac Ann. 2018;26(2):114–9.
18. Kawarada O, Otsuka F, Miki K, et al. Heterogeneous vascular response after implantation of bare nitinol self-expanding stents in the swine femoropopliteal artery. Cardiovasc Interv Ther. 2023;38(2):210–22.
19. Sakaoka A, Souba J, Rousselle SD, et al. Different vascular responses to a Bare Nitinol Stent in Porcine femoral and femoropopliteal arteries. Toxicol Pathol. 2019;47(3):408–17.
20. Dick P, Sabeti S, Mlekusch W, et al. Conventional balloon angioplasty versus peripheral cutting balloon angioplasty for treatment of femoropopliteal artery in-stent restenosis: initial experience. Radiology. 2008;248(1):297–302.
21. Cannavale A, Tsetis D, Krokidis M. The endovascular approach for in-stent restenosis in femoropopliteal disease. Expert Rev Cardiovasc Ther. 2015;13(4):391–401.
22. Zhen Y, Ren H, Chen J, et al. Systematic review and Meta-analysis of drug-coated balloon angioplasty for In-Stent restenosis in Femoropopliteal Artery Disease. J Vasc Interv Radiol. 2022;33(4):368–e746.
23. Krankenberg H, Tübler T, Ingwersen M, et al. Drug-coated balloon Versus Standard Balloon for superficial femoral artery In-Stent restenosis: the randomized femoral artery In-Stent restenosis (FAIR) trial. Circulation. 2015;132(23):2230–6.
24. Katsanos K, Spiliopoulos S, Reppas L, et al. Debulking atherectomy in the peripheral arteries: is there a role and what is the evidence? Cardiovasc Intervent Radiol. 2017;40(7):964–77.
25. Loffroy R, Edriss N, Goyault G, et al. Percutaneous mechanical atherothrombectomy using the Rotarex(®)S device in peripheral artery in-stent restenosis or occlusion: a French retrospective multicenter study on 128 patients. Quant Imaging Med Surg. 2020;10(1):283–93.
26. Freitas B, Steiner S, Bausback Y, et al. Rotarex Mechanical Debulking in Acute and Subacute arterial lesions. Angiology. 2017;68(3):233–41.
27. Bulvas M, Sommerová Z, Vaněk I, et al. Prospective single-arm trial of endovascular mechanical debulking as initial therapy in patients with Acute and Subacute Lower Limb Ischemia: one-year outcomes. J Endovasc Ther. 2019;26(3):291–301.
28. Freitas B, Bausback Y, Schuster J, et al. Thrombectomy devices in the treatment of Acute Mesenteric Ischemia: initial single-center experience. Ann Vasc Surg. 2018;51:124–31.
29. Wissgott C, Kamusella P, Andresen R. [Treatment of in-stent reocclusions of femoropopliteal arteries with mechanical rotational catheters]. Rofo. 2011;183(10):939–44.
30. Kronlage M, Printz I, Vogel B, et al. A comparative study on endovascular treatment of (sub)acute critical limb ischemia: mechanical thrombectomy vs thrombolysis. Drug Des Devel Ther. 2017;11:1233–41.
31. Liao CJ, Song SH, Li T, et al. Combination of Rotarex Thrombectomy and Drug-Coated Balloon for the treatment of Femoropopliteal Artery In-Stent restenosis. Ann Vasc Surg. 2019;60:301–7.
32. Loffroy R, Falvo N, Galland C, et al. Percutaneous rotational mechanical atherectomy plus thrombectomy using Rotarex S device in patients with Acute and Subacute Lower Limb Ischemia: a review of Safety, Efficacy, and outcomes. Front Cardiovasc Med. 2020;7:557420.
33. Gandini R, Del Giudice C, Merolla S, et al. Treatment of chronic SFA in-stent occlusion with combined laser atherectomy and drug-eluting balloon angioplasty in patients with critical limb ischemia: a single-center, prospective, randomized study. J Endovasc Ther. 2013;20(6):805–14.
34. Li X, Zhou M, Ding Y, et al. A systematic review and meta-analysis of the efficacy of debulking devices for in-stent restenosis of the femoropopliteal artery. J Vasc Surg. 2020;72(1):356–e665.

Publisher's note