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Original Article

Directional Atherectomy for Treating In-Stent Restenosis of the Superficial Femoral Artery

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Purpose: The optimal treatment for in-stent restenosis (ISR) of the superficial femoral artery (SFA) is still in debate. This study aimed to evaluate the safety and effectiveness of directional atherectomy (DA) as a primary treatment modality for ISR in SFA.

Materials and Methods: A retrospective single-center analysis was conducted. In total, 617 stents were deployed in 242 limbs for SFA diseases during the study period. ISR was identified in 29 limbs (12.0%); 14 limbs were treated with DA and 15 limbs with balloon angioplasty (BAP) alone. Technical success rate, target lesion revascularization (TLR) and patency rates (PRs) at 12 months, and any complications were evaluated.

Results: DA group included complete occlusions in 50% of patients and BAP group included in 40%. Mean improvement in the ankle-brachial index was 0.29 and 0.32, respectively (P=0.638). Technical success was achieved in all patients. The procedural success rates were 85.7% and 73.3%, respectively (P=0.651). There was no significant difference regarding residual stenosis, distal embolization, or flow-limiting dissection. Primary PRs at 1 year were 85.7% and 73.3%, secondary PRs were 100.0% and 93.3%, and TLR rates were 14.3% and 20.0% (P=0.411, 0.326, and 0.684, respectively).

Conclusion: Short-term outcomes after DA for ISR were not different from those after BAP but showed a tendency of better primary PR and TLR. Larger multicenter prospective studies are needed to define the role of DA in ISR treatment.

Key Words: Femoral artery, Directional atherectomy, Balloon angioplasty, Vascular patency, Vascular graft restenosis, Stents

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INTRODUCTION

Recent widening of indication for stenting in peripheral arterial disease has naturally led to an increase in the occurrence of in-stent restenosis (ISR). ISR is the Achilles heel of stenting, resulting in a reduced patency rate (PR) and increased target lesion revascularization (TLR). In previous reports, ISR in the superficial femoral artery (SFA) is highly prevalent in more than one third of patients at 1 year and up to 49% of them at 2 years [1-4].

Treatment of SFA ISR with conventional percutaneous transluminal angioplasty carries a higher rate of TLR at 1 year (31% to 47%) and reduced PRs (28% to 37%) [5-7]. Several strategies have been attempted to treat SFA ISR to

improve the results of endovascular treatment of SFA ISR. Cutting balloon and cryoplasty showed no advantage [8,9]. However, in the RELINE trial, which compared Viabahn (W. L. Gore & Associates, Flagstaff, AZ, USA) to plain old balloon angioplasty, the use of a covered stent to treat SFA ISR has shown significantly superior PR and freedom from TLR at 1 year (74.8% and 79.9%, respectively) [10]. However, the SALVAGE study yielded conflicting and disappointing results, that is, a primary PR of 48%, with a low TLR rate (17.4%) at 1 year [11]. Unfortunately, explanations for these conflicting results were variable, and the optimal therapy for ISR is not yet well defined.

The SilverHawk™ Plaque Excision System (Medtronic, Minneapolis, MN, USA) has primarily been designed for excision and removal of heavily calcified lesions in native arteries. The authors have hypothesized that removal of in-stent restenotic tissue using the SilverHawk directional atherectomy (DA) device followed by balloon angioplasty (BAP) would reduce restenosis rate, although this technique is an off-label use.

This study aimed to evaluate the safety and effectiveness of the SilverHawk DA device as a primary treatment modality for ISR in SFA and compare the outcomes with those of only BAP.

MATERIALS AND METHODS

1) Study design

A retrospective cross-sectional study was conducted among patients with ISR in the SFA between August 2005 and October 2015 in Seoul National University Hospital. Patients were excluded if they had de novo lesions, multiple tandem lesions that required treatment of index vessels simultaneously during the index procedure, or a treatment history of ISR. Technical and procedural success rates, PR, and TLR rates at 1 year, and any complications were evaluated by reviewing patients' medical records. Obtained data included clinical evaluation of symptoms, adverse limb events, ankle-brachial index (ABI) measurements, imaging studies of duplex ultrasonography (DUS), computed tomographic angiography, or digital subtraction angiography (DSA). The outcomes were compared between the two groups of DA and BAP alone. This study was approved by the Institutional Review Board of Seoul National University Hospital (IRB number: H-2003-155-1111) and informed consent was waived due to the retrospective design.

2) Definitions

ISR was defined as a 50% or greater narrowing of a previously stented artery by DUS (systolic velocity ratio no greater than 2.0) or DSA. Technical success was defined as the ability to achieve final residual angiographic stenosis of no greater than 30%. Procedural success was defined as achieving technical success and absence of complications such as distal embolization or flow-limiting dissection. Primary PR was defined as a patency within the target lesion without occlusion or TLR. Secondary PR was defined as patency obtained using additional surgical or endovascular procedure after occlusion.

3) Procedure detail

Treatment modalities were chosen according to the decision of the interventionalist. All atherectomy procedures were performed percutaneously under fluoroscopic guidance with insertion of a distal filter. Additional BAP after atherectomy was performed in all cases. Completion angiography of the distal arterial bed was performed routinely to detect any distal embolization. Dual antiplatelet medications were administered in all patients, if not contraindicated.

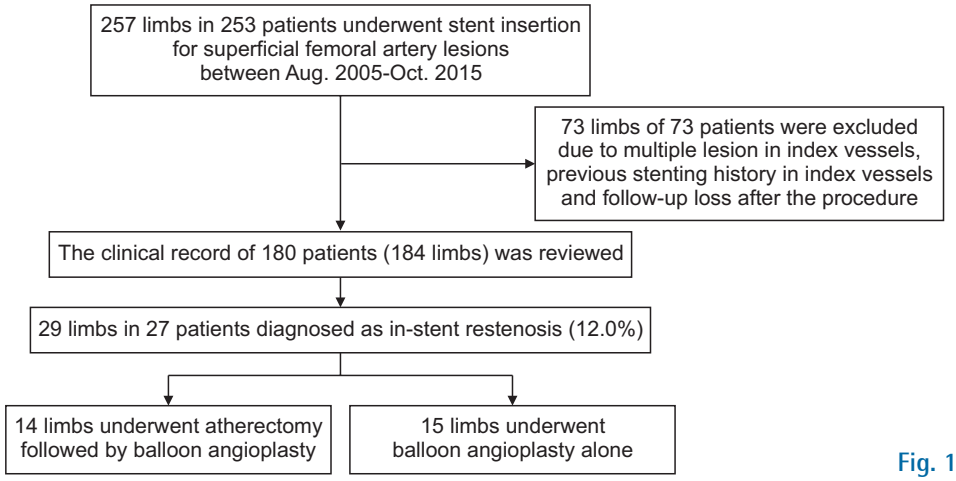

Fig. 1. Overview of patient enrollment.

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Table 1. Patients' baseline characteristics

Characteristic	DA (n=14)[a]	BAP (n=15)[b]	P-value
Patients			
Mean age (y)	69.5±8.7	73.7±7.8	0.180
Sex, male	14 (100.0)	13 (86.7)	0.164
Hypertension	13 (92.9)	13 (86.7)	0.600
Diabetes mellitus	10 (71.4)	12 (80.0)	0.605
Cardiovascular disease	4 (28.6)	5 (53.3)	0.524
Current smoker	6 (42.9)	6 (40.0)	0.352
Indication			0.164
Symptom aggravation	12 (85.7)	11 (73.3)	
Abnormal image finding	2 (14.3)	4 (26.7)	
Ankle-brachial index	0.62±0.19	0.62±0.20	0.957

Values are presented as mean±standard deviation or number (%).
DA, directional atherectomy; BAP, balloon angioplasty.
[a]DA followed by BAP group. [b]BAP only group.

4) Statistical analysis

Continuous data are presented as mean±standard deviation, and categorical data are presented as counts or percentage. Univariate analysis was carried out to compare the two treatment modalities. Cox multivariate regression analysis was performed to verify specific factors associated with TLR with the following variables: patient characteristics, lesion characteristics, angiographic characteristics, and each treatment modality. The results are presented as hazard ratio and 95% confidence interval. P<0.05 were considered to indicate statistical significance. All statistical analyses were performed with SPSS software (ver. 11.0; SPSS Inc., Chicago, IL, USA).

RESULTS

In total, 617 stents were deployed in 242 limbs (236 patients) for SFA diseases during the study period and satisfied the inclusion/exclusion criteria (Fig. 1). ISR was identified in 29 limbs (27 patients, 12.0%); 14 limbs (13 patients) were treated with excisional atherectomy using the SilverHawk device, and 15 limbs (14 patients) were treated by BAP only. Baseline characteristics of patients are shown in Table 1. The indication for treatment was aggravation of claudication symptoms in 85.7% and 73.3% of limbs, and abnormal ABI and image findings in 14.3% and 26.7% of limbs, respectively.

Details on the angiographic variables are summarized in Table 2. Complete occlusions were included in 50% of patients in the DA group and 40% of them in the BAP group. Average implant duration, lesion length, and luminal stenosis showed no significant difference (P=0.147, P=0.160, and P=0.454, respectively). Previous stent type was not significantly different in both groups. In the DA group, self-expanding stents were used in 12 limbs (85.7%)

Table 2. Angiographic variables (baseline stent and lesion characteristics)

Variable	DA (n=14)[a]	BAP (n=15)[b]	P-value
Symptom recurrence	12 (85.7)	11 (73.3)	0.429
Localization			0.897
Right	5 (35.7)	5 (33.3)	
Left	9 (64.3)	10 (66.7)	
Stents			
Implant interval (mo)	33.6±33.4	21.3±21.0	0.041
Length (mm)	176.6±130.3	140.7±68.0	0.370
Diameter (mm)	6.7±0.9	6.4±0.5	0.258
Restenosis lesions			
Length (mm)	131.3±54	105.2±111	0.160
Stenosis grade (%)	88.6 ±15.6	83.8±27.9	0.584
Complete occlusion	7 (50.0)	6 (40.0)	0.602
Adjunctive balloon			1.0
Plain balloon	11 (78.6)	11 (73.3)	
Drug-coated balloon	3 (21.4)	4 (26.7)	
Balloon diameter (mm)	6.4±0.6	6.5±0.7	
Ankle-brachial index			
Pre-procedural	0.64±0.22	0.59±0.19	0.570
Post-procedural	0.90±0.14	0.89±0.12	0.814
Mean improvement	0.29±0.15	0.32±0.23	0.638

Values are presented as number (%) or mean±standard deviation.
DA, directional atherectomy; BAP, balloon angioplasty.
[a]DA followed by BAP group. [b]BAP only group.

Table 3. Outcomes following treatment

Outcomes	DA (n=14)[a]	BAP (n=15)[b]	P-value
Immediate			
Technical success	14 (100.0)	15 (100.0)	1.0
Procedural success	12 (85.7)	11 (73.3)	0.651
Residual stenosis >30%[c]	1 (7.1)	0 (0.0)	0.483
Distal embolization[d]	1 (7.1)	2 (13.3)	1.0
Flow-limiting dissection[e]	0 (0.0)	2 (13.3)	0.483
One-year follow-up			
Ankle-brachial index	0.82±0.17	0.80±0.19	0.124
Primary patency	12 (85.7)	11 (73.3)	0.411
Target lesion revascularization	2 (14.3)	3 (20.0)	0.684
Secondary patency	14 (100.0)	14 (93.3)	0.326

Values are presented as number (%) or mean±standard deviation.
DA, directional atherectomy; BAP, balloon angioplasty.
[a]DA followed by BAP group. [b]BAP only group. [c]Treated by repeated BAP. [d]Treated by aspiration embolectomy. [e]Treated by bailout stenting.

(SMART®, Cordis-Johnson and Johnson, Warren, NJ, USA; Zilver Flex®, Cook Medical, Bloomington, IN, USA; Absolute Pro®, Abbott Vascular, Santa Clara, CA, USA; LifeStent®, Bard Peripheral Vascular, Inc., Tempe, AZ, USA; Complete SE®, Medtronic; Wallstent™, Boston Scientific, Natick, MA, USA). A balloon-expandable stent (Express® LD; Boston Scientific) was used in 1 limb (7.1%), and a self-expanding drug-eluting stent (Zilver PTX®; Cook Medical) was deployed in 1 limb. In the BAP group, all stents were self-expanding.

The outcomes are listed in Table 3. Technical success was achieved in all patients in both groups, and procedural success was achieved in 85.7% of the atherectomy group, and 73.3% of the angioplasty group, with no significant differences (Fig. 2). Complications are also shown in Table 3. In the DA group, 1 (7.1%) patient had a residual stenosis of more than 30%. Repeated BAP was carried out as an additional procedure (Fig. 3A). One patient had distal embolization requiring aspiration. In the BAP group, 2 (13.3%) patients had distal embolization and were also treated with aspiration. Two patients had a flow-limiting dissection after the procedure. Bailout stent insertions with self-expandable stents (SMART) were performed (Fig. 3B). Three (21.4%) patients in the DA group were treated with drug-coated balloons (DCB), and two Lutonix™ DCB catheters (Bard) and one InPACT™ Admiral™ (Medtronic). In the angioplasty group, 4 (26.7%) patients were treated with InPACT DCB catheters. The portion of DCB usage was not significantly different.

The 1-year outcomes are presented in Table 3. The ABIs significantly improved after treatment in both groups (0.64 to 0.90 in the DA group and 0.59 to 0.89 in the BAP group).

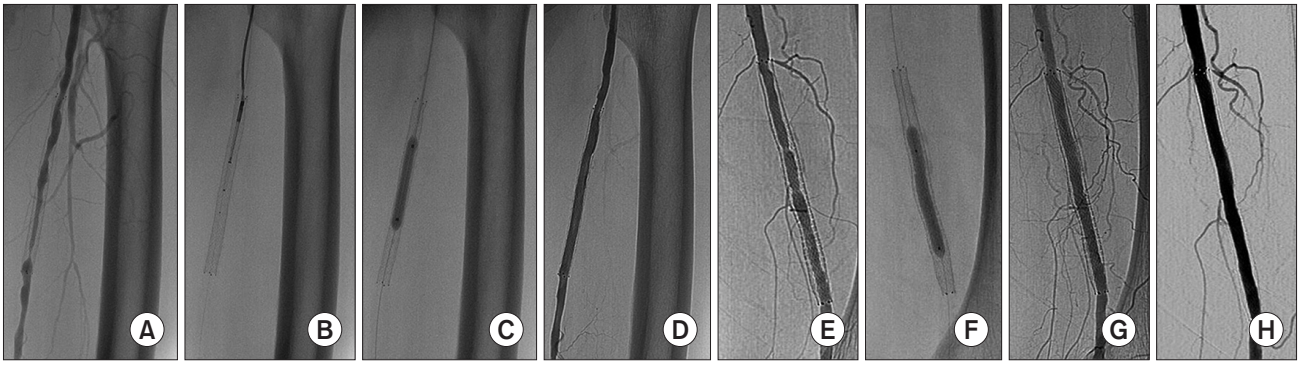

Fig. 2. (A-D) SilverHawk atherectomy device for in-stent restenosis (ISR) of the superficial femoral artery. (A) Initial angiography showed multiple ISR. (B) Directional atherectomy was performed. (C) Additional balloon angioplasty was performed. (D) Completion angiography showed restoration of good flow without residual stenosis. (E-H) Balloon angioplasty for ISR of the superficial femoral artery. (E) Initial angiography showed ISR. (F) Angioplasty was performed using a plain old balloon. (G) Luminal gain was obtained. (H) Completion angiography showed restoration of flow without residual stenosis.

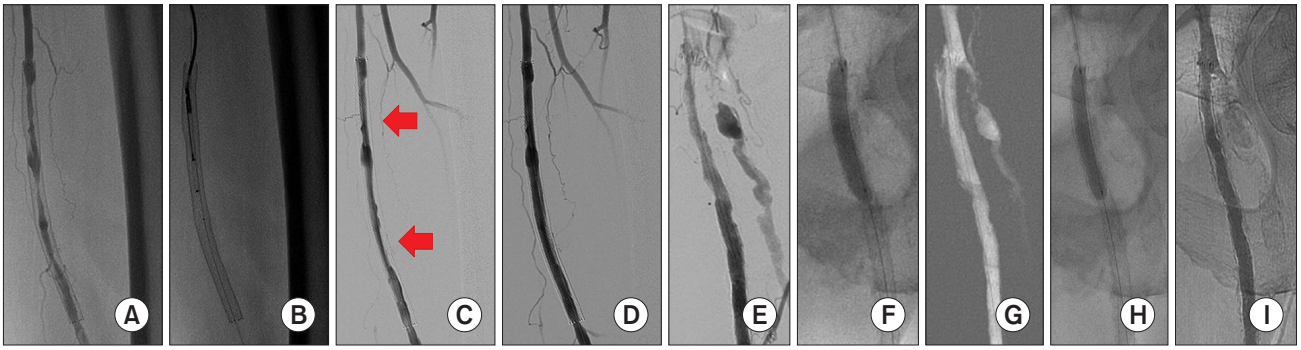

Fig. 3. (A-D) Suboptimal result of directional atherectomy (DA). (A) Initial angiography showed multiple in-stent restenosis (ISR). (B) DA was followed by balloon angioplasty. (C) The suboptimal procedural result showed residual stenosis (red arrows). (D) The completion angiography after repeated balloon angioplasty showed luminal gain with restoration of the superficial femoral artery flow. (E-I) Suboptimal result of balloon angioplasty. (E) Initial angiography showed multiple ISR. (F) Plain old balloon angioplasty was done. (G) Proximal dissection developed with suboptimal procedural result. (H) Bailout stenting was performed. (I) Completion angiography showed luminal gain with restoration of flow without residual stenosis.

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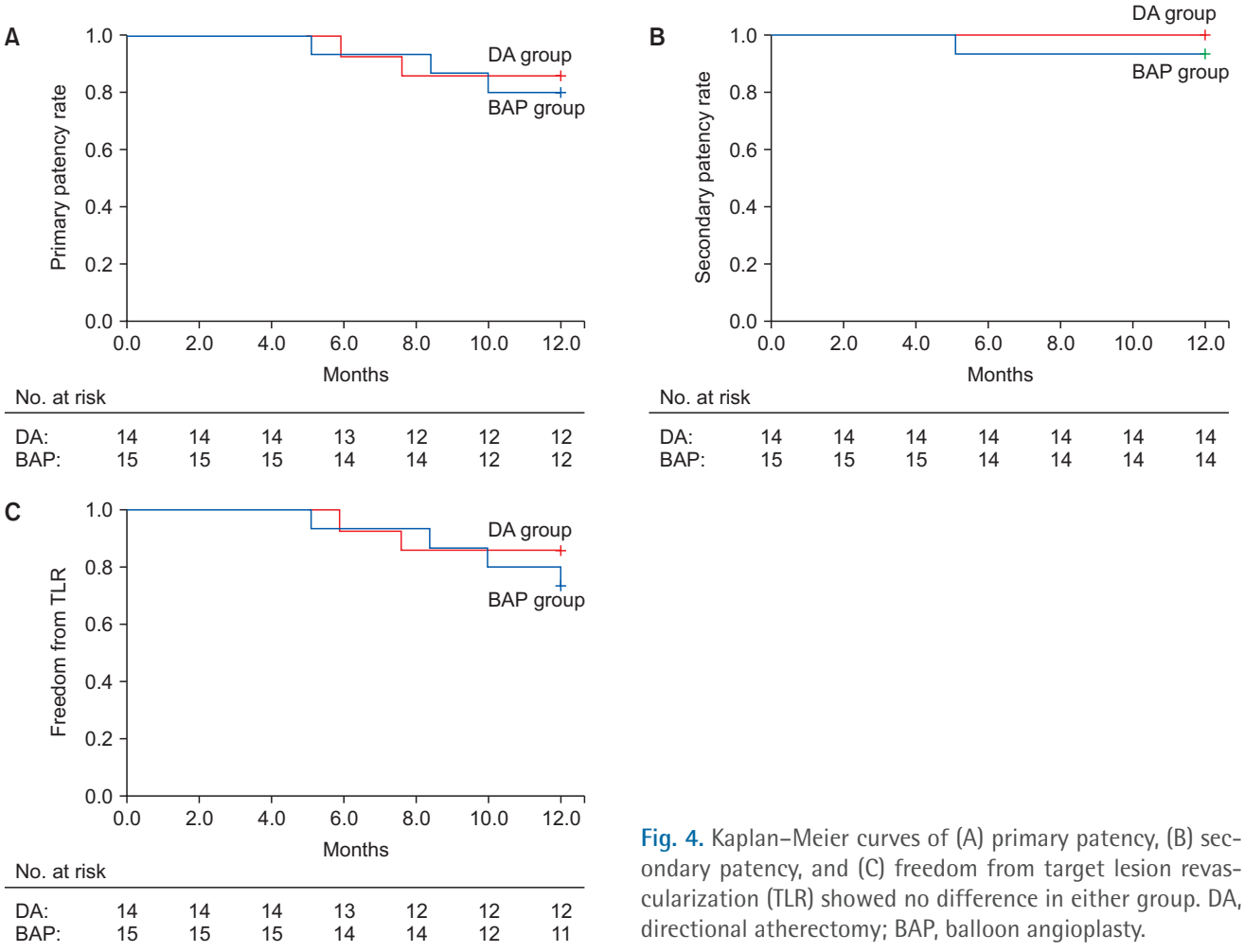

Fig. 4. Kaplan–Meier curves of (A) primary patency, (B) secondary patency, and (C) freedom from target lesion revascularization (TLR) showed no difference in either group. DA, directional atherectomy; BAP, balloon angioplasty.

There were no significant differences in either group (P=0.570, 0.814, and 0.638, respectively). Primary PRs at 1 year were 85.7% and 73.3%, secondary PRs were 100.0% and 93.3%, and TLR rates were 14.3% and 20.0% (P=0.411, 0.326, and 0.684, respectively). Kaplan–Meier curves for patencies and freedom from TLR showed no significant differences between the groups (Fig. 4). Cox multivariate regression analysis was performed to verify specific risk factors associated with TLR; however, there were no factors showing significant differences.

DISCUSSION

Although several strategies have been attempted to treat SFA ISR, there is no consensus on optimal treatment with excellent long-term patency. In this study, we report the results of DA with the SilverHawk Plaque Excision System. This device has not been approved for treating ISR due to concerns of the device cutter getting stuck on the stent struts. However, the device is easy to operate, yielding high technical success rates in primary vessel stenosis with a primary success rate up to 82% to 100% [12-14]. We hypothesized that it can be safely applied in ISR if done carefully by experienced vascular specialists.

The immediate outcomes showed no significant difference between the two modalities. There was no device-stent interaction during the DA procedure unlike the aforementioned concerns. To prevent such unintended adverse events, intravascular ultrasound (IVUS) is an effective device that can visualize the arterial wall structures and the severity of intraluminal disease in 3-dimensional images, providing a more precise assessment of completeness during procedures [15,16]. These reports also showed better outcomes with IVUS than with angiography alone in primary stenosis. IVUS-guided optimized atherectomy could be an optimal technique for treating ISR. Unfortunately, IVUS is not routinely available in Korea because the device is not reimbursed by health insurance yet. Our technical tip to prevent the device-stent interaction is to make good utilization of the magnification view.

In addition, the DA group achieved a high technical success rate (85.7%), with little need for additional procedures

such as aspiration embolectomy due to distal embolization (1 case), or bailout stenting due to flow-limiting dissection (1 of 14 cases, 7.1%). However, these results were not significantly different in comparison to that of the angioplasty group, which had a technical success rate of 73.3% (P=0.651) and a similar proportion of additional procedure rates such as aspiration embolectomy or bailout stenting (2 of 15 cases, 13.3% each). Distal embolization is a frequent adverse event during peripheral arterial interventions [17-19]. The use of atherectomy devices has a higher risk of distal embolization [20,21]. In the EXCITE trial, distal embolization occurred in 8.3% of SFA ISR patients treated with laser despite the use of distal protection in 40.2% of cases [5]. In our institution, distal embolic protection is routinely performed when using the atherectomy device but not for simple BAP. In our study, there was one (7.1%) patient in the DA group and two (13.3%) patients in the angioplasty group who had distal embolization, which was found at the end of the procedure and treated with aspiration thromboembolectomy. The completion angiography showed no residual thrombus and confirmed flow restoration. According to previous reports, embolic protection is commonly used worldwide during infrainguinal interventions [5,18]. Some surgeons warned that the use of an atherectomy device in SFA ISR is a strong predictor of distal embolization and an increased rate of unexpected adverse event [18,19]. Although the result of our study shows no difference in adverse event rates in both groups, routine filter usage during treatment of infrainguinal ISR, especially during atherectomy technique, is recommended despite adversely affecting the cost.

The DA group showed a tendency of better primary PR and TLR, but there was no significant difference. Primary PRs at 1 year in the DA vs. BAP groups were 85.7% and 73.3% (P=0.411), TLR rates were 14.3% and 20.0% (P=0.684), and secondary PRs were 100.0% and 93.3% (P=0.326), respectively. However, despite data showing no significant benefit of DA over BAP in this study, the debulking plus the use of DCB strategy might be a promising treatment option for SFA ISR. DCB is a promising new technology that appears to improve PR and reduces the need for TLR in de novo SFA lesions [21,22]. Furthermore, atherectomy was very effective in tissue debulking, allowing deeper and higher antiproliferative drug diffusion in the vessel wall. To improve the long-term results, DCB after DA could be the best combined therapy. DCBs with DA showed a good PR of 84.7% at 1 year, supporting the rationale for combining atherectomy and DCB [23]. Studies are currently underway to assess the long-term outcomes of atherectomy in combination with DCB [24,25].

Limitations of this study are to be noted. This was not a randomized study including a reference group undergoing percutaneous BAP and it was limited by its small number of patients. Only 1-year results are analyzed and long-term results are not available yet. The treatment modalities were chosen according to the interventionalist's preference, thus introducing selection bias for BAP in simpler lesions and DA for more difficult lesions. The interval from stenting to treatment ISR was longer in the DA group, which may cause another selection bias. Further, patients treated with plain balloons or DCB are both included in the study groups. These could have an effect on the results of this study.

CONCLUSION

Short-term outcomes after DA for ISR were not different to BAP but showed a tendency for better primary PR and TLR. Larger multicenter prospective studies are needed to define the role of DA in ISR treatment, especially combined with DCB.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHOR CONTRIBUTIONS

Concept and design: SC, SKM. Analysis and interpretation: SC, AH, SA. Data collection: SC. Writing the article: SC, SKM. Critical revision of the article: AH, SA, SM, JH, HJJ, SKM. Final approval of the article: all authors. Statistical analysis: SC. Obtained funding: none. Overall responsibility: SKM.

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