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Original Article

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Outcomes of Dissection Angles as Predictor of Restenosis after Drug-Coated Balloon Treatment

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Aim: The predictors of restenosis after endovascular therapy (EVT) with paclitaxel drug-coated balloons (DCBs) have not been clearly established. The present study aimed to investigate the association of post-procedural dissection, as evaluated using intravascular ultrasound (IVUS), with the risk of restenosis following femoropopliteal EVT with paclitaxel DCBs.

Methods: In the present single-center retrospective study, 60 de novo femoropopliteal lesions (44 patients) that underwent EVT with DCBs, without bail-out stenting, were enrolled. The primary outcome was 1-year primary patency. Risk factors for restenosis were evaluated using a Cox proportional hazards regression model and random survival forest analysis.

Results: The 1-year primary patency rate was 57.2% [95% confidence interval, 45%–72%]. IVUS-evaluated post-procedural dissection was significantly associated with the risk of restenosis ($P=0.002$), with the best cutoff point of 64° [range, 39°–83°]. The random survival forest analysis showed that the variable importance measure of IVUS-evaluated dissection was significantly lower than that of the reference vessel diameter ($P<0.001$), not different from that of the lesion length ($P=0.41$), and significantly higher than that of any other clinical feature (all $P<0.05$).

Conclusion: IVUS-evaluated post-procedural dissection was associated with 1-year restenosis following femoropopliteal EVT with DCB.

Key words: Drug-coated balloon, Intravascular ultrasound, Dissection, Restenosis, Peripheral artery disease

Abbreviations: EVT, endovascular treatment; DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty; IVUS, intravascular ultrasound; TLR, target lesion reintervention; CD-TLR, clinically driven TLR; ROC, receiver operating characteristics

Introduction

Femoropopliteal peripheral artery disease is one of the most common life-threatening and lifestyle-limiting diseases[1, 2]. According to current guideline recommendations[3], endovascular treatment (EVT) is a treatment of choice widely performed[4]. The patency of EVT using paclitaxel drug-coated balloons (DCBs) has been reported to be superior compared to percutaneous transluminal angioplasty (PTA) using uncoated balloons[5-7]. Severe dissection evaluated using angiography has been reported as an important risk factor for restenosis following PTA with uncoated balloons[8]; however, predictors of restenosis have not been clearly established.

Intravascular ultrasound (IVUS) imaging provides detailed, high-quality, real-time images. Predictors of restenosis that were not detected by angiogra-

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phy have been identified using IVUS studies following implantation of bare nitinol stents and drug-eluting stents[9, 10]. The superiority of IVUS over angiography in detecting dissection has been previously reported[11]. We hypothesized that IVUS evaluation provides information additional to that provided by angiography in predicting restenosis following EVT with DCBs.

Aim

The present study aimed to investigate the association of post-procedural dissection, as evaluated using IVUS, with the risk of restenosis following femoropopliteal EVT with DCBs, without bail-out stenting.

Methods

Study Population

This single-center retrospective study enrolled patients who underwent EVT with DCBs, without bail-out stenting, for de novo or native vessel restenotic lesions in the femoropopliteal arteries under IVUS guidance between February 2018 and May 2019. The exclusion criteria were restenosis of stents or surgical bypass. Of the 88 consecutive de novo femoropopliteal lesions (69 patients), 28 were excluded for the following reasons: treated with DCBs before approval ($n=14$), lost to follow-up ($n=7$), missing data of post-intervention IVUS ($n=5$), and bail-out stenting ($n=2$). Finally, 60 lesions (44 patients) that underwent EVT with DCBs, but without bail-out stenting, were evaluated.

Protocol

Heparin (5000 IU) was administered after sheath insertion, and additional heparin was administered to maintain an active clotting time of >200 s. Either ipsilateral or contralateral femoral puncture was selected depending on the condition of the iliac artery and/or the position of the femoral bifurcation. Predilation was performed in all cases. After successful balloon angioplasty, patients were treated with the DCBs, either Lutonix (C.R. Bard, Murray Hill, NJ, USA) or IN.PACT Admiral (Medtronic Vascular, Santa Clara, CA, USA). IVUS images were obtained pre- and post-EVT using an AltaView (Terumo Corporation, Tokyo, Japan), OptiCross (Boston Scientific, Marlborough, MA, USA) or Eagle Eye Platinum catheter (Philips Volcano, Rancho Cordova, CA, USA), which was pulled back through the lesion for image capture.

In cases where pre-EVT IVUS was performed, balloon size was selected according to the IVUS image. The distal reference mean diameter was measured, and an equivalent balloon size was selected. The balloon was inflated to its nominal or rated pressure for >180 seconds. The type of balloon, type of DCB, balloon inflation time, balloon pressure, and type of IVUS depended on the operator's discretion.

Dual anti-platelet therapy consisting of aspirin (100 mg/day) and clopidogrel (75 mg/day) or prasugrel (3.75 mg/d) was continued for at least 1 month after EVT. Subsequent therapies were at the discretion of the treating physicians.

Quantitative IVUS Analysis

The post-procedure IVUS data were analyzed using computerized planimetry software (echo Plaque; INDEC Medical Systems, Santa Clara, CA, USA). The minimal lumen area (MLA) and maximum dissection angle were evaluated based on the whole lesion. The dissection angle was measured using an electronic protractor centered on the lumen **(Fig. 1)**.

Outcomes and Definitions

The primary outcome was the 1-year primary patency rate. Primary patency was defined as a peak systolic velocity <2.5 as measured by duplex ultrasound at rest without any target lesion reintervention (TLR)[11]. Secondary outcomes were 1-year clinically driven TLR (CD-TLR), major amputation, and all-cause death. CD-TLR was defined as any reintervention performed for >50% stenosis identified by duplex ultrasound with recurrent clinical symptoms. Procedural success was defined as <30% residual stenosis without flow-limiting dissection after EVT. Angiographic dissection[12], the Peripheral Artery Calcium Scoring System (PACSS)[13], Rutherford[14], and Trans-Atlantic Inter-Society Consensus (TASC II)[15] classifications scores were assessed according to previous reports.

Statistical Analysis

The baseline characteristics are presented as means and standard deviations for continuous variables or as percentages for discrete variables, if not otherwise mentioned. A histogram was plotted to depict the distribution of IVUS-evaluated dissections; the descriptive statistics are presented as the median and interquartile range. A P-value <0.05 was considered statistically significant, and 95% confidence intervals are reported when appropriate. The primary patency and freedom from restenosis rates following EVT were analyzed using the Kaplan–Meier method. The association between IVUS-evaluated dissection and the risk of restenosis was investigated using the Cox proportional hazards regression model with a

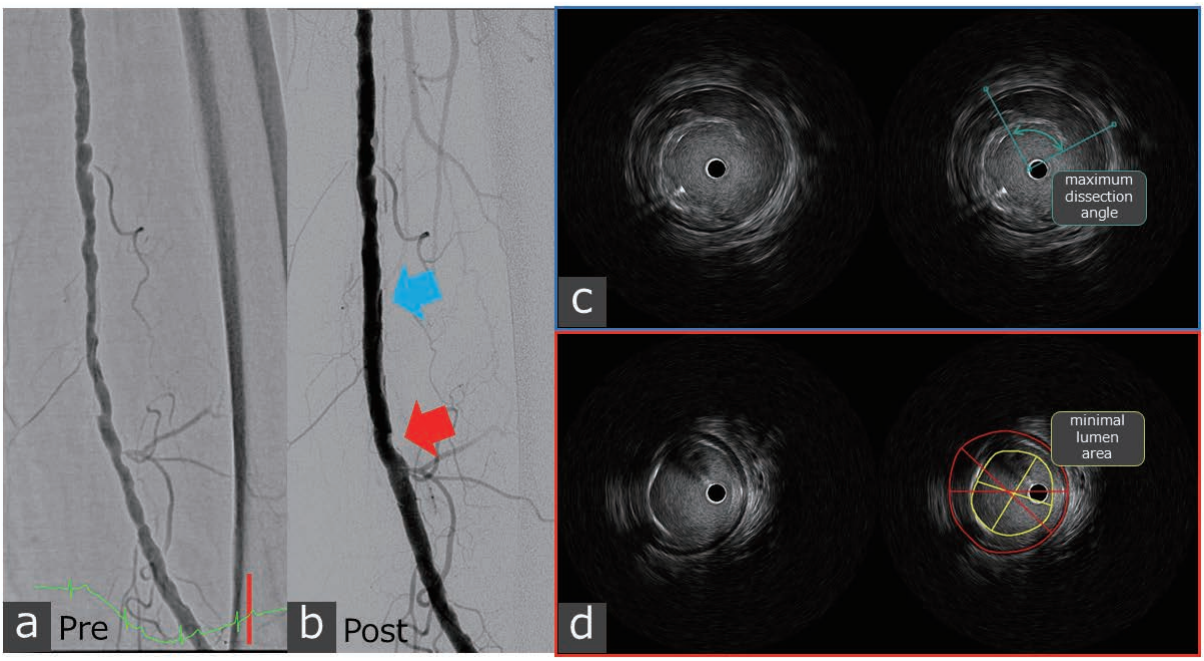

Fig. 1. A representative case

(a). Pre angiography (b) Post Paclitaxel DCB treatment angiography. The maximum dissection site is indicated with blue arrow and minimal lumen area site in red arrow (c) IVUS image and measurement of maximum dissection (blue arrow in panel b) (d) IVUS image and measurement of minimal lumen area (red arrow in panel b).
DCB, drug-coated balloon; IVUS, intravascular ultrasound

spline function. The predictive ability of factors for 1-year restenosis risk was evaluated using a time-dependent receiver operating characteristic (ROC) curve[16]; the area under the curve (equivalent to concordance (C) statistic) and the maximum Youden's index (or Youden's J statistic, defined as the sum of sensitivity and specificity minus one) were calculated. The sensitivity and specificity corresponding to the respective cutoff points were also estimated. Predictive contributions were compared between IVUS-evaluated dissection and other clinical features according to their variable importance measures derived from a random survival forest analysis[17]. *P*-values and 95% confidence intervals for the time-dependent ROC analysis and the random survival forest analysis were obtained by 2000-time bootstrap resampling. All statistical analyses were performed using R v3.6.0 (R Development Core Team, Vienna, Austria).

The institutional review board of the participating institution approved the study, and the study was done in accordance to the Declaration of Helsinki. The requirement for informed consent was waived because of the retrospective study design, where existing medical records were used. Relevant information regarding the study is available to the public in accordance with the Ethical Guidelines for Medical and Health Research Involving Human Subjects.

Results

The baseline characteristics of the study population are summarized in **Table 1**. The mean age was 74 ± 8 years and chronic limb-threatening ischemia (Rutherford ≥ 4) was present in 22% of patients. **Fig. 2a** illustrates the histogram of IVUS-evaluated dissections; the median (interquartile range) dissection angle was 70° (41°–93°). A mean follow-up period was 10.1 ± 3.4 months. The 1-year primary patency rate was 57.2% (95% confidence interval, 45%–72%; **Fig. 2b**), and the 1-year CD-TLR rate was 20%. There were no major amputations or deaths reported during the study period.

As illustrated in **Fig. 2c**, the IVUS-evaluated post-procedural dissection was significantly associated with the risk of restenosis ($P = 0.002$). The risk of restenosis almost had a linear increase up to approximately 110°, and the risk plateaued beyond that angle **(Fig. 2c)**. Time-dependent ROC analysis revealed that the area under the curve (C statistic and 95% confidence interval) was 0.77 (0.64–0.88). The maximum Youden's index was 0.46 (0.24–0.67), which corresponded to the cutoff point of 64° (39°–83°). The

Table 1. Patient and limb characteristics

Patient characteristics	(*n* = 44)
Sex	32 (73%)
Age, years	74 ± 8
Current smoking	14 (32%)
Hypertension	38 (86%)
Hyperlipidemia	38 (86%)
Diabetes mellitus	33 (75%)
Renal impairment	
eGFR ≥ 60 ml/min/1.73 m^2	22 (50%)
eGFR = 30–60 ml/min/1.73 m^2	15 (34%)
eGFR = 15–30 ml/min/1.73 m^2	1 (2%)
eGFR < 15 ml/min/1.73 m^2 or on dialysis	6 (14%)
Aspirin use	44 (100%)
P2Y12 inhibitor use	43 (98%)
Anticoagulant use	10 (23%)
Statin use	30 (68%)
Limb characteristics	(*n* = 60)
Rutherford classification	
Category 2	30 (50%)
Category 3	17 (28%)
Category 4	3 (5%)
Category 5	7 (12%)
Category 6	3 (5%)
Ankle brachial index	0.76 ± 0.20
(missing data)	1 (2%)
Lesion characteristics	(*n* = 60)
Reference vessel diameter (mm)	4.8 ± 0.8
(missing data)	1 (2%)
Chronic total occlusion	7 (12%)
Lesion length (mm)	127 ± 78
PACSS classification	
Grade 0	37 (62%)
Grade 1	4 (7%)
Grade 2	7 (12%)
Grade 3	3 (5%)
Grade 4	9 (15%)
TASC II classification	
Class A	19 (32%)
Class B	13 (22%)
Class C	9 (15%)
Class D	19 (32%)
Below-the-knee runoff	
1 runoff	27 (45%)
2 runoffs	27 (45%)
3 runoffs	6 (10%)

Procedure characteristics	(*n* = 60)
Pre dilation	60 (100%)
Scoring balloon	18 (30%)
Non-compliant balloon	27 (45%)
Post dilation	4 (6.7%)
DCB	
Lutonix	47 (78%)
IN.PACT	13 (22%)
Residual stenosis	
0%	2 (3%)
10%	23 (38%)
20%	14 (23%)
30%	15 (25%)
40%	4 (7%)
50%	2 (3%)
Angiographic dissection	
None	4 (7%)
A	11 (18%)
B	16 (27%)
C	23 (38%)
D	6 (10%)
IVUS-evaluated post -procedural minimal lumen area (mm^2)	12.6 ± 4.4

eGFR, estimated glomerular filtration rate; P2Y12, platelet adenosine diphosphate receptor; PACSS, peripheral artery calcification scoring system; TASC, Trans-Atlantic Inter-Society Consensus; DCB, drug-eluting balloon; IVUS, intravascular ultrasound.
Data are expressed as the mean ± standard deviation or number (percentage).

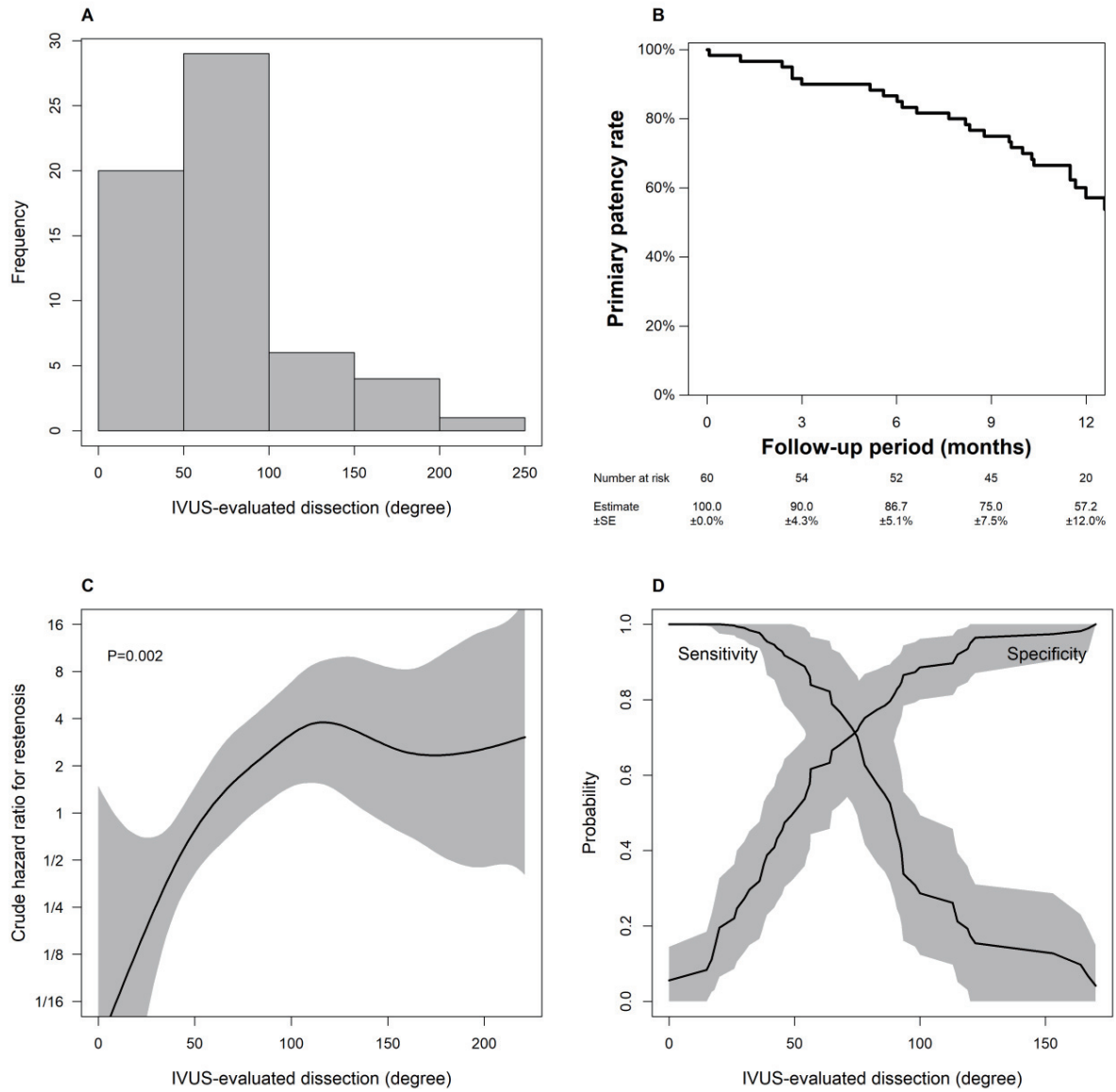

Fig. 2. IVUS-evaluated dissection and restenosis risk

(a) Histogram of IVUS-evaluated dissection. (b) Kaplan–Meier estimates of primary patency rate. (c) Association of IVUS-evaluated dissection with restenosis risk. (d) Sensitivity and specificity for 1-year restenosis risk corresponding to the respective cutoff points of IVUS-evaluated dissection. Shaded areas in panels c and d indicate 95% confidence intervals.
IVUS, intravascular ultrasound

sensitivity and specificity at this cutoff point was 84% (43%–96%) and 62% (37%–80%), respectively **(Fig. 2d)**.

The random survival forest analysis showed that the variable importance measure of IVUS-evaluated dissection was significantly lower than that of the reference vessel diameter ($P<0.001$), not different from that of the lesion length ($P=0.41$), and significantly higher than that of any other clinical feature (all $P<0.05$), which indicated the predictive importance of the reference vessel diameter followed by IVUS-evaluated dissection **(Fig. 3)**.

When we performed a bivariate Cox regression model for restenosis risk in which an IVUS-evaluated dissection angle of 64°or larger and the reference vessel diameter were entered as the explanatory variables, the resulting hazard ratios were 3.72 ($P=0.042$) and 0.35 per 1 mm increase ($P=0.002$), respectively. These indicate that an IVUS-evaluated dissection angle of 64° or larger was associated with an increased risk of restenosis independently of the reference vessel diameter.

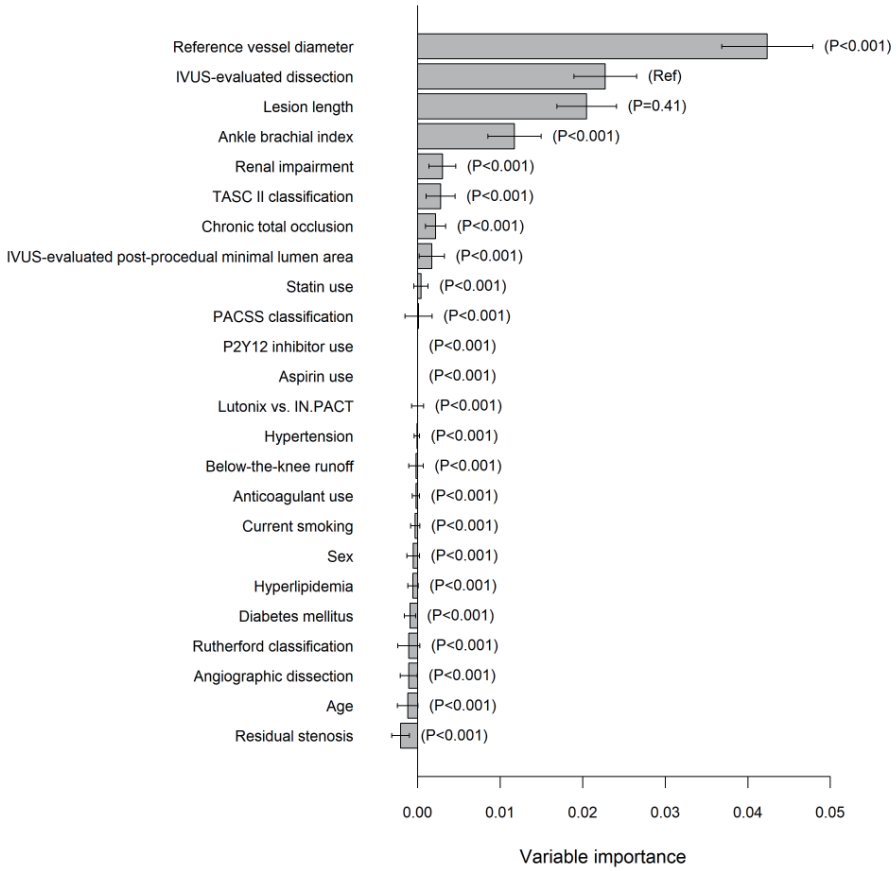

Fig. 3. Variable importance in the random survival forest analysis

Error bars indicate 95% confidence intervals.
IVUS, intravascular intrasound; TASC, TransAtlantic Inter-Society Consensus; PACSS, peripheral artery calcification scoring system; P2Y12, platelet adenosine diphosphate receptor

Discussion

To the best of our knowledge, this is the first study to evaluate the outcomes of EVT with DCBs using IVUS. The main findings of the present study were as follows: (1) the IVUS-evaluated post-procedural dissection predicted restenosis following DCB treatment and (2) the variable of the highest importance for predicting restenosis was the distal reference vessel diameter followed by IVUS-evaluated dissection and lesion length.

The difference between EVT with and without stents lies in whether the dissection persists at the culprit site. Because dissections as a result of balloon angioplasty are covered by stents when stent implantation is done, dissection is no longer a predictor of restenosis following EVT with stents. In contrast, severe dissection detected by angiography has been reported as an important predictor of restenosis following EVT with uncoated balloons[8]. Severe dissection was believed to be a predictor of restenosis following EVT with DCBs. However, Tepe *et al.* reported that the severity of dissection detected by angiography was not a predictor of restenosis following EVT with DCBs[18].

Angiography is the gold standard for evaluating dissection following balloon angioplasty; however, there are some limitations to this approach[19]. First, evaluation using angiography underestimates the number of dissections. Second, angiographic evaluation cannot evaluate the circumference of the dissection. Third, the evaluation is affected by the procedure (i.e., injection speed and dose of contrast agent). Finally, it carries an inherent risk of contrast-induced nephropathy, especially in patients with chronic kidney disease. IVUS has been reported to help identify 4–6 times more dissections than angiography[11].

The present study findings revealed that angiography-evaluated post-procedural dissection could not predict restenosis. In contrast, IVUS-evaluated dissec-

tion could predict restenosis following EVT with DCBs. The degree of dissection was less than 100º in the majority of cases with a median angle of 70.5º. The degree of dissection was linearly associated with restenosis risk up to 110º, and the risk plateaued when the degree of dissection was greater than 110º. The best cutoff point for predicting restenosis was 64º. Spearman's correlation coefficient between angiography-evaluated and IVUS-evaluated dissection was 0.17 ($P = 0.20$).

Female sex, diabetes, dialysis, critical limb ischemia, long lesion length, and poor run-off are known predictors of restenosis following self-expandable nitinol stenting for femoropopliteal lesions[20]. Another study used IVUS and reported that long lesion length, not taking cilostazol, and a small reference vessel diameter were associated with restenosis following self-expandable nitinol stenting[9]. The Zephyr registry revealed that long lesion length, small distal reference vessel area, and small minimum stent area were predictors of restenosis following EVT with a drug-eluting stent[10].

Factors associated with restenosis following EVT with DCBs are not clearly established. A study demonstrated that long lesion length was associated with restenosis[21]. Lesion length and reference vessel diameter were also reported as predictive factors of 2-year revascularization of the target lesion following DCB treatment[22]. In the present study, small vessel size and long lesion length were predictors of restenosis. To identify the outcomes of IVUS-evaluated dissection on restenosis, we performed the random survival forest analysis. The association of IVUS-evaluated dissection was equivalent to that of lesion length, following the most important factor, vessel size.

In our study, the patency rate was relatively low, even with DCBs, especially in cases of large angle IVUS-evaluated dissection. We believe there are two possible explanations for this issue: severe baseline lesion characteristics due to a real-world clinical setting and very low rates of bail-out stenting. A similar patency rate has been reported in a previous real-world study[21]. Since DCBs combined with stents for the treatment of these kind of lesions are not currently approved in our country, the bail-out stent rate in our study was only 2%, remarkably low when compared to previous real-world studies[21, 22].

Although flow-limiting severe dissection is a widely accepted criterion for bail-out stenting after balloon angioplasty, stenting may be an option in cases of IVUS-evaluated severe dissection, even if blood flow is adequate, to increase patency rates. Recently, new-generation drug-eluting stents have been introduced with very high patency rates compared with first generation drug-eluting stents[23]. IVUS evaluation following angioplasty with a non-coated balloon might affect the strategy selection between new generation drug-eluting stent implants and DCBs. Further evaluations using IVUS may enable us to identify lesions suitable specifically for DCBs or stents.

It is advantageous to perform EVT with DCBs and avoid stent implantation because the latter may limit future treatments. Vessel preparation by minimizing the angle of dissection could improve the patency rate following EVT with DCBs. Several atherectomy devices have been demonstrated to reduce the rate of dissections[24, 25]. Recently, Karashima et al. reported that using non-slip element balloons was effective in reducing severe dissection following PTA[26]. Even with plain balloon angioplasty, using a long balloon and long inflation time have been reported to reduce the rates of severe dissections[27, 28]. Further interventional prospective studies are warranted for evaluating the utility of these devices and techniques to improve the patency rates following EVT with DCBs.

This study has some limitations. The present study was a non-randomized, retrospective, single-center study with a small patient cohort. Selection bias and a heterogeneous population sample cannot be ruled out. The heterogeneity of patency rate according to the hospital volume has been reported[29]. The sample size was too small and observed events (i.e., restenosis) were too scarce; therefore, we were unable to conduct further detailed explanatory analyses. Further studies are needed to externally validate the current findings. Moreover, the use of IVUS during EVT is not financed in many countries as of today.

Conclusion

IVUS-evaluated post-procedural dissection was associated with restenosis at 1-year follow-up after femoropopliteal EVT with DCB.

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Notice of Grant Support

None.

Conflict of Interest

None.

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