Diagn Interv Radiol 2023; DOI: 10.4274/dir.2023.232114

INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Propensity score-matched analysis of six-month outcomes of paclitaxel-coated balloons combined with UltraScore balloons versus conventional scoring balloons for femoropopliteal lesions

Takuya Haraguchi
Masanaga Tsujimoto
Ryo Otake
Yoshifumi Kashima
Katsuhiko Sato
Tsutomu Fujita

PURPOSE

Combination angioplasty with paclitaxel-coated balloons (PCBs) and conventional scoring balloons for femoropopliteal lesions has demonstrated satisfactory results, even for complex lesions. The UltraScore balloon (Becton Dickinson, New Jersey, USA), which has a maximum length of 300 mm, has two longitudinal 0.010-inch stainless steel wires and is a new treatment option for complex femoropopliteal lesions. However, no studies have evaluated the effect of the UltraScore balloon on femoropopliteal lesions. This study aimed to compare the clinical efficacy of angioplasty over a six-month period using UltraScore balloons versus conventional scoring balloons for the treatment of atherosclerotic femoropopliteal lesions with PCBs.

METHODS

A retrospective single-center observational study enrolled 272 patients who underwent PCB angioplasty combined with an UltraScore balloon (n = 58) or conventional scoring balloon (n = 214) without bailout stenting. Propensity score matching was used to minimize intergroup differences in baseline characteristics, and six-month outcomes were compared between the two groups. The primary endpoint was a technical success (i.e., residual angiographic stenosis of <30% with non-severe dissection). The secondary endpoints were the incidences of periprocedural complications, restenosis, and target lesion revascularization (TLR).

RESULTS

After propensity score matching, 50 matched pairs of patients were selected for analysis. The UltraScore group had a significantly longer vessel length (192.8 ± 94.9 versus 36.6 ± 7.9 mm, $P < 0.001$), a lower frequency of non-compliant balloon (26.0% versus 56.0%, $P = 0.002$), and a smaller PCB diameter (5.32 ± 0.65 versus 5.66 ± 0.52 mm, $P = 0.002$) compared with the scoring group. The primary endpoint of technical success was significantly higher in the UltraScore group than in the scoring group (76.0% versus 56.0%, $P = 0.035$). There were no significant differences in periprocedural complications (4.0% versus 2.0%, $P = 0.562$), six-month restenosis (4.0% versus 8.0%, $P = 0.339$), and TLR (2.0% versus 4.0%, $P = 0.500$) between both groups. The multivariate logistic regression analysis showed that UltraScore use was independently associated with an increase in technical success (odds ratio: 2.58; 95% confidence interval: 1.05–6.36, $P = 0.040$).

CONCLUSION

The use of an UltraScore balloon during PCB angioplasty for femoropopliteal lesions significantly improved technical success compared with conventional scoring balloons. UltraScore use was an independent predictor of technical success, indicating its potential advantages in peripheral intervention procedures.

KEYWORDS

Balloon angioplasty, endovascular treatment, UltraScore balloon, conventional scoring balloon, cutting balloon, drug-coated balloon, femoropopliteal lesions, peripheral artery disease

From the Department of Cardiology (T.H. ✉t.haraguchi@scvc.jp, M.T., R.O., Y.K., K.S., T.F.), Asia Medical Group, Sapporo Heart Center, Sapporo Cardio Vascular Clinic, Sapporo, Japan.

Received 16 January 2023; revision requested 22 February 2023; accepted 16 March 2023.

Epub: 17.04.2023

Publication date: 30.05.2023

DOI: 10.4274/dir.2023.232114

You may cite this article as: Haraguchi T, Tsujimoto M, Otake R, Kashima Y, Sato K, Fujita T. Propensity score-matched analysis of six-month outcomes of paclitaxel-coated balloons combined with UltraScore balloons versus conventional scoring balloons for femoropopliteal lesions. *Diagn Interv Radiol.* 2023;29(3):535-541.

Endovascular therapy has been a standard treatment for femoropopliteal lesions due to its improved device performance over other treatments. Several studies have demonstrated satisfactory results after paclitaxel-coated balloon (PCB) angioplasty for femoropopliteal lesions.[1-3] However, severely calcified lesions, particularly concentric calcifications, present a challenge in achieving adequate lumen enlargement and paclitaxel absorption by PCB angioplasty, leading to increased restenosis risk.[4] Therefore, proper vessel preparation is essential to ensure good PCB outcomes; additionally, a larger minimum lumen area is associated with a decreased risk of restenosis.[5]

Conventional scoring balloons have been used for severely calcified or poorly dilated lesions. Conventional scoring balloon angioplasty has been found to restore larger lumen gain and reduce the incidence of severe dissection compared with plain balloon angioplasty in short femoropopliteal lesions.[6,7] However, the short length of conventional scoring balloons limits their use in long lesions. The UltraScore balloon (Becton Dickinson, New Jersey, USA), which has a maximum length of 300 mm, has two longitudinal 0.010-inch stainless steel wires and is a new treatment option for complex femoropopliteal lesions, including longer lesions. However, no studies have evaluated the effect of the UltraScore balloon on femoropopliteal lesions. This study aims to compare the clinical efficacy of angioplasty over a six-month period using UltraScore balloons versus conventional scoring balloons for the treatment of atherosclerotic femoropopliteal lesions with PCBs.

Methods

Study population

This study retrospectively and non-randomly analyzed symptomatic atherosclerotic femoropopliteal lesions in 731 patients (Rutherford classification 2 and 6) treated with a PCB without a bailout stent procedure from July 2018 to June 2022 at Sapporo Heart Center. Of this total, the following 459 patients were excluded based on treatment type: standard balloons (n = 398), scaffolds (n = 19), in-stent lesions (n = 14), and restenosis after PCB angioplasty (n = 27). Finally, this study enrolled 272 patients (272 limbs; average age 76.9 ± 9.3 years; female 37.1%). The present study compared the periprocedural and clinical outcomes for up to six months between patients treated with conventional scoring balloons (n = 214) and those treated with UltraScore balloons (n = 58) for vessel preparation before PCB use. The Cutting balloon (n = 54; Boston Scientific, Marlborough, Massachusetts, USA) and the AngioSculpt (n = 160; Philips, San Diego, California, USA) were used in the scoring group. All participants were asked to visit our center 6 ± 1 months after PCB angioplasty to evaluate for restenosis occurrence. A propensity score-matched analysis was conducted as described in the statistical analysis section. The study protocol was designed in accordance with the Declaration of Helsinki and was approved by the Sapporo Heart Center Ethics Committee of our institution (approval no: 20230001). Informed consent was obtained from all participants or their family members before using the balloon for comparison in this study.

Main points

- The UltraScore balloon improved technical success in femoropopliteal lesions during paclitaxel-coated balloon angioplasty more than conventional scoring balloons.
- Comparable six-month outcomes were observed between the groups using UltraScore and conventional scoring balloons.
- UltraScore balloon use was an independent predictor of technical success.

Endovascular procedures and medical therapy

The indication for endovascular treatment for symptomatic femoropopliteal lesions was a >70% diameter stenosis with Rutherford classification categories between 2 and 6. The femoropopliteal vasculature was treated in a single session. The approach site for each common femoral artery was determined based on the location of the lesion, and a 6-Fr sheath was inserted. A 5.000-IU dose of unfractionated heparin was subsequently injected from the sheath, targeting an activated coagulation time of >250 s. A 0.014- or 0.035-inch guidewire was used to cross the lesions. The selection of different types of balloons was based on the morphology and location of the lesions. The UltraScore and conventional scoring balloons were primarily used in complex lesions such as long lesions, chronic total occlusions (CTO), and severe calcifications that were difficult to dilate with conventional balloon angioplasty. Angiography-or intravascular ultrasound (IVUS)-evaluated balloon diameters were used. Standard balloon and PCB angioplasties were performed to cover the lesion as completely as possible. The choice of balloon (UltraScore, Cutting balloon, and AngioSculpt) and PCB (IN.PACT Admiral: Medtronic, Santa Clara, USA; Ranger: Boston Scientific, Marlborough, USA; and Lutonix: Becton Dickinson, New Jersey, USA) was determined at the operator's discretion, taking into consideration factors such as lesion length, degree of stenosis, and the presence of occlusions or calcifications. These factors were evaluated case by case to determine each patient's most appropriate treatment strategy. Post-dilation was performed if the residual stenosis after PCB angioplasty was >50% using a balloon that was appropriately sized and selected based on angiography or IVUS evaluation. Patients who underwent the bailout stent procedure were excluded. Atherectomy devices were not used because they were unavailable in Japan during the study period. Hemostasis was achieved using manual compression or device closure.

After the intervention, patients were prescribed daily doses of 100 mg aspirin and 75 mg clopidogrel for three months. Patients who received anticoagulation therapy were prescribed a regular dose of aspirin and clopidogrel for one month. The patients were then switched to long-term anticoagulation and aspirin therapy.

Study endpoints

The primary endpoint was technical success, defined as residual angiographic stenosis of less than 30% with non-severe dissection, classified as a dissection grade from none to type C according to the National Heart, Lung, and Blood Institute classification system for coronary arteries.[8] Secondary endpoints included periprocedural complications, defined as intraoperative complications within seven days postoperatively; restenosis rate at six months, defined as a target lesion with significant stenosis (a peak systolic velocity ratio >2.4 on duplex ultrasound at intervals of one and six months or >50% stenosis on digital subtraction angiography or computed tomography angiography); and target lesion revascularization (TLR) at six months, defined as repeat endovascular or surgical bypass procedures for limbs with recurrent symptoms accompanied by recurrent stenosis >50% as measured by angiography.

Statistical analysis

The baseline characteristics of the study were summarized as mean ± standard deviation for continuous variables and frequency (percentage) for categorical variables unless otherwise specified. The unpaired t-test or

chi-square test was used to compare continuous or categorical variables between the two groups. A *P* value of <0.050 was considered statistically significant. Propensity score matching was performed to minimize the intergroup differences in baseline characteristics. The propensity score was calculated using a binary logistic regression model that included sex, hypertension, diabetes mellitus, hemodialysis, chronic limb-threatening ischemia, lesion length >150 mm, coronary artery disease, CTO, and bilateral calcification as explanatory variables. Matching of the two groups was performed using the logit of the propensity score, within a caliper of 0.2 standard deviations of the logit of the propensity score (caliper 0.029), to ensure balance in the baseline characteristics between the two groups. We extracted as many matched samples as possible to maximize the statistical power for detecting intergroup prognostic differences. After matching, intergroup differences were analyzed with stratification by pairs, and weighted descriptive statistics were reported to provide a comprehensive overview of the data. The balance in baseline characteristics between the groups was assessed with the standardized difference. Patient characteristics, treatment strategies, and clinical outcomes were compared between patients treated using the UltraScore and conventional scoring balloons (Cutting balloon or AngioSculpt). Descriptive statistics were used to summarize the baseline and outcome variables. Independent predictors of technical success were determined using multivariate logistic regression, including all univariate parameters with a *P* value of <0.100, and 95% confidence intervals were reported where appropriate. Statistical analyses were performed using IBM SPSS Statistics software version 29.0.

Results

This study included 272 patients, with 58 patients (21.3%) receiving treatment with UltraScore balloons. After propensity score matching, 50 matched pairs of patients were selected for analysis. Baseline patient and lesion characteristics were comparable between the two groups, as presented in Table 1. Procedural characteristics are summarized in Table 2. In vessel preparation, the UltraScore group had a significantly longer length (192.8 ± 94.9 versus 36.6 ± 7.9 mm, *P* < 0.001), a lower frequency non-compliant balloon (26.0% versus 56.0%, *P* = 0.002), and smaller PCB diameter (5.32 ± 0.65 versus 5.66 ± 0.52 mm, *P* = 0.002) compared with the scoring group.

Table 3 presents the postprocedural outcomes of the two groups. The primary endpoint of technical success was significantly higher in the UltraScore group than in the scoring group (76.0% versus 56.0%, *P* = 0.035). Residual stenosis <30% was achieved more frequently in the UltraScore group than in the scoring group (90.0% versus 68.0%, *P* = 0.007), whereas non-severe dissection was similar in both groups (86.0% versus 84.0%, *P* = 0.779). There were no significant differences in periprocedural complications (4.0% versus 2.0%, *P* = 0.562), six-month restenosis (4.0% versus 8.0%, *P* = 0.339), and TLR (2.0% versus 4.0%, *P* = 0.500) between the two groups. The arterial dissection patterns, summarized

Table 1. Patient and lesion characteristics

	Overall population (before matching)			Matched population		
Variable	UltraScore n = 58	Scoring n = 214	*P* value	UltraScore n = 50	Scoring n = 50	*P* value
Age, y	76.9 ± 9.6	76.9 ± 9.3	0.997	76.7 ± 9.5	78.3 ± 9.9	0.399
Female	27 (46.6)	74 (34.6)	0.094	23 (46.0)	22 (44.0)	0.841
Body mass index, kg/m^2	22.9 ± 3.7	22.6 ± 3.8	0.556	23.0 ± 3.6	23.1 ± 3.8	0.882
Ambulatory	41 (70.7)	161 (75.2)	0.483	38 (76.0)	36 (72.0)	0.648
Hypertension	45 (78.9)	185 (86.9)	0.136	41 (82.0)	41 (82.0)	-
Dyslipidemia	35 (61.4)	137 (64.6)	0.653	31 (62.0)	33 (66.0)	0.677
Diabetes mellitus	36 (63.2)	119 (56.1)	0.341	32 (64.0)	32 (64.0)	-
Current smoker	10 (17.5)	51 (23.8)	0.312	10 (20.0)	15 (30.0)	0.248
Chronic renal disease	40 (70.2)	125 (59.2)	0.132	36 (72.0)	31 (62.0)	0.288
Hemodialysis	15 (26.3)	47 (22.5)	0.545	12 (24.0)	9 (18.0)	0.461
Coronary artery disease	20 (34.5)	134 (62.6)	<0.001	20 (40.0)	20 (40.0)	-
Cerebrovascular disease	10 (17.5)	31 (14.9)	0.625	9 (18.0)	10 (20.0)	0.799
Heart failure	10 (17.5)	29 (14.0)	0.505	10 (20.0)	6 (12.2)	0.295
Antiplatelet therapy	50 (86.2)	198 (92.5)	0.122	42 (84.0)	47 (94.0)	0.112
Anticoagulation	9 (15.8)	30 (14.0)	0.735	8 (16.0)	6 (12.0)	0.564
Statin	33 (57.9)	107 (50.0)	0.289	29 (58.0)	26 (52.0)	0.546
Preprocedural ankle–brachial index	0.59 ± 0.30	0.69 ± 0.28	0.018	0.59 ± 0.30	0.64 ± 0.30	0.208
Rutherford classification	3.9 ± 1.2	3.5 ± 1.1	0.026	3.8 ± 1.3	3.6 ± 1.0	0.298
Chronic limb-threatening ischemia	28 (49.1)	78 (36.6)	0.086	23 (46.0)	18 (36.0)	0.309
Preoperative stenosis (%)	93.0 ± 8.5	90.7 ± 9.5	0.085	93.2 ± 8.1	93.6 ± 8.6	0.803
Reference vessel diameter, mm	4.3 ± 0.9	4.7 ± 1.0	0.019	4.4 ± 0.8	4.6±1.0	0.183
Lesion length, mm	222.9 ± 106.9	133.0 ± 109.0	<0.001	214.8 ± 107.5	216.8 ± 113.3	0.928
Chronic total occlusion	17 (29.3)	40 (18.7)	0.078	15 (30.0)	15 (30.0)	-

Table 1. Continued

	Overall population (before matching)			Matched population		
Variable	UltraScore n = 58	Scoring n = 214	*P* value	UltraScore n = 50	Scoring n = 50	*P* value
TASC II classification						
A	5 (8.6)	80 (37.4)	<0.001	5 (10.0)	8 (16.0)	0.372
B	9 (15.5)	54 (25.2)	0.120	8 (16.0)	5 (10.0)	0.372
C	37 (63.8)	66 (30.8)	<0.001	30 (60.0)	32 (64.0)	0.680
D	7 (12.1)	14 (6.5)	0.162	7 (14.0)	5 (10.0)	0.538
Calcification graded by PACSS grade						
0	9 (15.5)	65 (30.4)	0.024	8 (16.0)	9 (18.0)	0.790
1	8 (13.8)	17 (7.9)	0.171	6 (12.0)	4 (8.0)	0.505
2	2 (3.4)	20 (9.3)	0.144	2 (4.0)	4 (8.0)	0.339
3	11 (19.0)	39 (18.2)	0.897	11 (22.0)	7 (14.0)	0.298
4	28 (48.3)	73 (34.1)	0.048	23 (46.0)	26 (52.0)	0.548
Below-the-knee artery poor runoff ≤1	25 (43.1)	66 (30.8)	0.079	20 (40.0)	19 (38.0)	0.838

Data are presented as number (percentage) or mean ± standard deviation unless otherwise specified. PACSS, peripheral artery calcium scoring system; TASC, TransAtlantic Inter-Society Consensus.

Table 2. Procedure characteristics

	Overall population (before matching)			Matched population		
Variable	UltraScore n = 58	Scoring n = 214	*P* value	UltraScore n = 50	Scoring n = 50	*P* value
Vessel preparation						
Diameter, mm	5.12 ± 0.59	5.37 ± 0.80	0.009	5.14 ± 0.57	5.34 ± 0.77	0.145
Diameter-to-artery ratio	1.22 ± 0.28	1.20 ± 0.36	0.654	1.19 ± 0.25	1.21 ± 0.33	0.804
Specific balloon length, mm	197.9 ± 95.9	34.8 ± 9.1	<.001	192.8 ± 94.9	36.6 ± 7.9	<0.001
Inflation pressure, atm	13.5 ± 2.7	13.5 ± 2.5	0.934	13.6 ± 2.6	14.0 ± 2.3	0.414
Cutting balloon	-	54 (25.2)	-	-	8 (16.0)	-
AngioSculpt	-	160 (74.8)	-	-	42 (84.0)	-
Semicompliant balloon	20 (34.5)	28 (13.1)	<0.001	18 (36.0)	14 (28.0)	0.391
Non-compliant balloon	15 (25.9)	79 (36.9)	0.116	13 (26.0)	28 (56.0)	0.002
Drug-coated balloon						
Model						
IN.PACT admiral	2 (3.4)	54 (25.2)	<0.001	12 (24.0)	2 (4.0)	0.004
Lutonix	14 (24.1)	120 (56.1)	<0.001	14 (28.0)	23 (46.0)	0.062
Ranger	42 (72.4)	40 (18.7)	<0.001	34 (68.0)	15 (30.0)	<0.001
Diameter, mm	5.28 ± 0.67	5.65 ± 0.58	<0.001	5.32 ± 0.65	5.66 ± 0.52	0.002
Diameter-to-artery ratio	1.25 ± 0.26	1.26 ± 0.34	0.816	1.23 ± 0.23	1.29 ± 0.34	0.310
Total length, mm	246.5 ± 109.5	150.0 ± 98.3	<0.001	239.0 ± 108.4	225.2 ± 101.6	0.256
Inflation pressure, atm	13.3 ± 2.9	13.2 ± 2.3	0.889	13.4 ± 2.7	14.0 ± 2.2	0.261
Inflation time, sec	165.5 ± 25.9	146.4 ± 29.8	<0.001	163.2 ± 27.2	152.4 ± 30.2	0.063
Additional balloon	4 (6.9)	22 (10.3)	0.439	4 (8.0)	5 (10.0)	0.500
Intravascular ultrasound use	14 (24.1)	49 (22.9)	0.843	13 (26.0)	14 (28.0)	0.822

Data are presented as number (percentage) or mean ± standard deviation unless otherwise specified.

in Figure 1 and Table 3, did not differ significantly between the two groups. The interaction analysis for restenosis is presented in Table 4. The multivariate logistic regression analysis showed that UltraScore balloon use was independently associated with an increase in technical success (odds ratio, 2.58; 95% confidence interval: 1.05–6.36, *P* = 0.040). The Rutherford classification improved similarly in both groups, as is shown in Figure 2.

Discussion

This study demonstrated that the use of UltraScore balloons during PCB angioplasty for femoropopliteal lesions resulted in a significantly higher technical success rate than conventional scoring balloons. UltraScore balloon use was identified as an independent predictor of technical success.

Conventional scoring balloons have been commonly used to treat severe calcifications and non-dilatable lesions, where conventional standard balloon angioplasty may not be effective. A previous study showed that scoring balloons were more effective than plain balloon angioplasty in plaque modification for short femoropopliteal lesions.[9] The success of balloon angioplasty was positively associated with scoring balloon use but inversely associated with CTO and longer lesion length. Another retrospective study comparing long and short balloons for femoropopliteal occlusions found that longer balloons decreased the frequency of dilation over the length of the lesion compared to shorter balloons, reducing the risk of balloon edge dissection and technical failure.[10] In this study, the UltraScore group had a significantly longer balloon length than the scoring group. The presence of two long wire elements on a long UltraScore balloon may have positively impacted vessel preparation and contributed to achieving a lower residual stenosis rate compared to conventional short-scoring balloons. Consequently, UltraScore balloon use was a significant positive factor for technical success. Furthermore, this study found that the severity of calcification, as graded by the Peripheral Artery Calcium Scoring System, CTOs, and long lesions did not impact technical success, suggesting that the scoring element of the balloons used in this study was effective in treating complex lesions, consistent with the results of a previous study.[9]

Drug-coated balloons (DCBs) have consistently demonstrated improved efficacy compared with standard balloon angioplasty in treating femoropopliteal lesions.[1-3] As such, DCB angioplasty is recommended as the first-line treatment for femoropopliteal lesions instead of uncoated balloon angioplasty.[11,12] Nevertheless, the rate of bailout stenting tended to be higher in longer lesions.[13] In this study, bailout stenting procedures per-

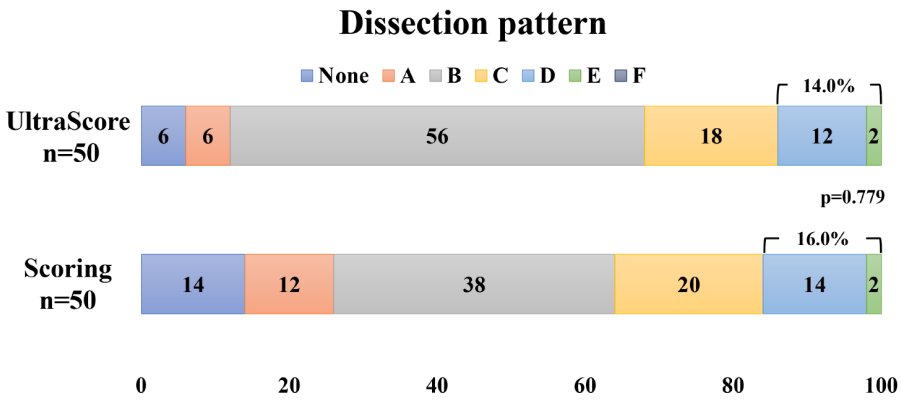

Figure 1. Comparison of dissection patterns between paclitaxel-coated balloon angioplasty with UltraScore and conventional scoring balloons (print color requested). The incidence of severe dissection, defined as type D or greater, was not significantly different between the two groups.

Table 3. Clinical outcomes of endovascular treatment

	Overall population (before matching)			Matched population		
Variable	UltraScore n = 58	Scoring n = 214	*P* value	UltraScore n = 50	Scoring n = 50	*P* value
Technical success	74.1% (43)	65.4% (140)	0.211	76.0% (38)	56.0% (28)	0.035
Residual stenosis <30%	89.6% (52)	70.6% (151)	0.003	90.0% (45)	68.0% (34)	0.007
Non-severe dissection; none to type C	84.5% (49)	88.8% (190)	0.375	86.0% (43)	84.0% (42)	0.779
Periprocedural complications	3.4% (2)	1.9% (4)	0.469	4.0% (2)	2.0% (1)	0.562
Restenosis rate at six months	3.4% (2)	4.2% (9)	0.796	4.0% (2)	8.0% (4)	0.339
Target lesion revascularization rate at six months	1.7% (1)	2.3% (5)	0.779	2.0% (1)	4.0% (2)	0.500
Postoperative stenosis (%)	14.6 ± 7.7	18.2 ± 13.4	0.103	2.5 ± 7.6	9.5 ± 15.1	0.004
Postoperative ankle–brachial index	0.89 ± 0.16	0.94 ± 0.18	0.062	0.92 ± 0.14	0.91 ± 0.15	0.746
Dissection pattern						
None	5.2% (3)	20.1% (43)	0.007	6.0% (3)	14.0% (7)	0.182
A	5.2% (3)	18.2% (39)	0.015	6.0% (3)	12.0% (6)	0.243
B	53.4% (31)	35.5% (76)	0.013	56.0% (28)	38.0% (19)	0.071
C	20.7% (12)	14.9% (32)	0.294	18.0% (9)	20.0% (10)	0.799
D	12.1% (7)	9.8% (21)	0.618	12.0% (6)	14.0% (7)	0.766
Flow-limited dissection	3.4% (2)	1.4% (3)	0.305	2.0% (1)	2.0% (1)	0.753

Data are presented as number (percentage) or mean ± standard deviation unless otherwise specified.

Table 4. Predictors of technical success

	Univariate analysis		Multivariate analysis	
Variables	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value
Female	1.26 (0.55–2.92)	0.582		
Ambulatory	1.04 (0.40–2.66)	0.939		
Diabetes mellitus	0.95 (0.40–2.26)	0.916		
Dyslipidemia	0.78 (0.33–1.88)	0.586		
Diabetes mellitus	1.24 (0.74–2.08)	0.409		
Hemodialysis	0.80 (0.29–2.16)	0.656		
Coronary artery disease	0.93 (0.40–2.16)	0.863		
Statin	0.79 (0.34–1.82)	0.582		
Distal reference vessel diameter <5.0 mm	0.57 (0.22–1.47)	0.249		
Lesion length <100 mm	2.81 (0.87–9.11)	0.085	1.90 (0.51–7.08)	0.338
Chronic total occlusion	0.46 (0.19–1.11)	0.083	0.42 (0.16–1.08)	0.072
PACSS grade 4	0.38 (0.16–0.89)	0.026	0.44 (0.17–1.16)	0.096
UltraScore use	2.49 (1.06–5.86)	0.037	2.58 (1.05–6.36)	0.040
Cutting balloon use	0.75 (0.16–3.41)	0.710		
IVUS use	0.54 (0.22–1.34)	0.183		

Data are presented as number (percentage) or mean ± standard deviation unless otherwise specified. PACSS, peripheral artery calcium scoring system; CI, confidence interval; IVUS, intravascular ultrasound.

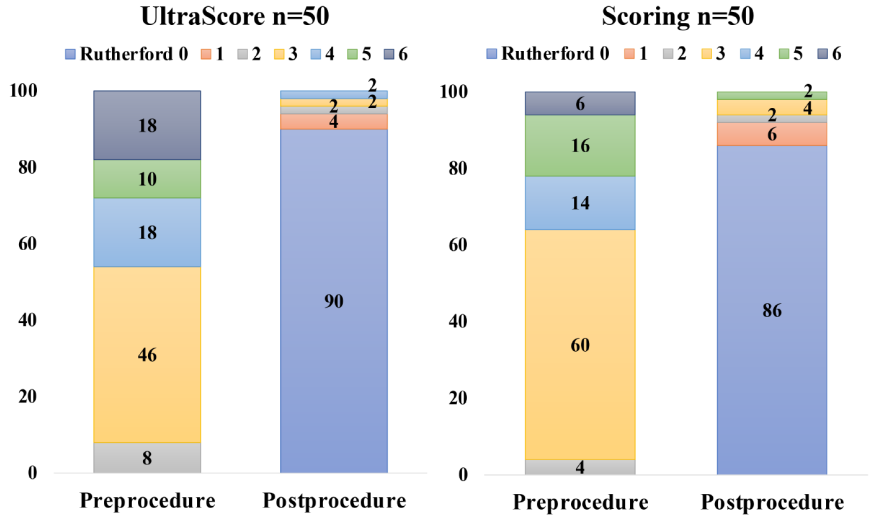

Figure 2. Change in Rutherford classification category before and after the procedure.

formed after PCB angioplasty were excluded, and acceptable rates of technical success, six-month restenosis, and TLR were observed in both groups, even though the study population had severe underlying lesions. Combining PCBs with scoring balloons, including UltraScore balloons, may improve paclitaxel's absorption and antiproliferative effects, resulting in better outcomes. The DCB-Trak registry, which used PCBs combined with the VascuTrak balloon (Becton Dickinson, New Jersey, USA), a scoring balloon with one longitudinal body wire, demonstrated good efficacy for short femoropopliteal lesions.[14] A previous case series using combination therapy with UltraScore and sirolimus-coated balloons (Selution SLR: MedAlliance SA, Nyon, Switzerland) also demonstrated satisfactory technical and procedural success.[15] However, the clinical outcomes of combining UltraScore balloons with PCBs had not been researched until the present study, which revealed that UltraScore balloons had a positive effect on longer femoropopliteal lesions and had similar effects to conventional scoring balloons for short to medium-length lesions. The results of this study suggest that combining PCBs with scoring balloons, including the UltraScore balloon, was a clinically effective treatment strategy for femoropopliteal lesions, with comparable six-month restenosis and TLR rates in both groups.

The current study had several limitations. First, it was a retrospective, single-center study with a small sample size, which may limit the generalizability of the findings. Second, the scoring group included only the Cutting balloon and AngioSculpt balloon; no other types of scoring balloons were included. The limited variety of balloons used may have affected the results. Third, no atherectomy devices were used. While previous studies have demonstrated the effectiveness and safety of using atherectomy devices followed by DCB angioplasty, these devices are expensive and mainly used as adjunctive treatments for focal lesions.[16,17] No studies have compared DCB combined therapy using atherectomy devices and scoring balloons. Furthermore, given the limited financial resources of the health system,[18] a cost-effectiveness analysis should be conducted in future randomized controlled trials evaluating the usefulness of these combination therapies. Finally, the follow-up period was only six months, and the long-term clinical outcomes of this combination therapy are unknown. Therefore, further studies with larger sample sizes and longer follow-up periods are necessary to confirm this study's results and evaluate the efficacy and safety of UltraScore and other scoring balloons in combination with PCB angioplasty.

In conclusion, this study demonstrated that using UltraScore balloons during PCB angioplasty for femoropopliteal lesions significantly improved technical success compared with conventional scoring balloons. UltraScore balloon use was an independent predictor of technical success. These results indicate the potential advantages of using

UltraScore balloons in peripheral intervention procedures.

Acknowledgements

The authors thank all the members of Sapporo Heart Center.

Conflict of interest disclosure

The authors declared no conflicts of interest.

References

1. Laird JA, Schneider PA, Jaff MR, et al. Long-term clinical effectiveness of a drug-coated balloon for the treatment of femoropopliteal lesions. *Circ Cardiovasc Interv*. 2019;12(6):e007702. [CrossRef]
2. Sachar R, Soga Y, Ansari MM, et al. 1-year results from the RANGER II SFA randomized trial of the ranger drug-coated balloon. *JACC Cardiovasc Interv*. 2021;14(10):1123-1133. [CrossRef]
3. Rosenfield K, Jaff MR, White CJ, et al. Trial of a paclitaxel-coated balloon for femoropopliteal artery disease. *N Engl J Med*. 2015;373(2):145-153. [CrossRef]
4. Fanelli F, Cannavale A, Gazzetti M, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. *Cardiovasc Intervent Radiol*. 2014;37(4):898-907. [CrossRef]
5. Horie K, Tanaka A, Taguri M, Inoue N. Impact of baseline and postprocedural intravascular ultrasound findings on 1-year primary patency after drug-coated balloon treatment of femoropopliteal lesions. *J Endovasc Ther*. 2022;29(1):66-75. [CrossRef]
6. Canaud L, Alric P, Berthet JP, Marty-Ané C, Mercier G, Branchereau P. Infrainguinal cutting balloon angioplasty in de novo arterial lesions. *J Vasc Surg*. 2008;48(5):1182-1188. [CrossRef]
7. Poncyljusz W, Falkowski A, Safranow K, Rać M, Zawierucha D. Cutting-balloon angioplasty versus balloon angioplasty as treatment for short atherosclerotic lesions in the superficial femoral artery: randomized controlled trial. *Cardiovasc Intervent Radiol*. 2013;36(6):1500-1507. [CrossRef]
8. Rogers JH, Lasala JM. Coronary artery dissection and perforation complicating percutaneous coronary intervention. *J Invasive Cardiol*. 2004;16(9):493-499. [CrossRef]
9. Horie K, Tanaka A, Taguri M, Inoue N. Impact of scoring balloons on percutaneous transluminal angioplasty outcomes in femoropopliteal lesions. *J Endovasc Ther*. 2020;27(3):481-491. [CrossRef]
10. Tan M, Urasawa K, Koshida R, et al. Comparison of angiographic dissection patterns caused by long vs short balloons during balloon angioplasty of chronic femoropopliteal occlusions. *J Endovasc Ther*. 2018;25(2):192-200. [CrossRef]
11. Feldman DN, Armstrong EJ, Aronow HD, et al. SCAI consensus guidelines for device selection in femoral-popliteal arterial interventions. *Catheter Cardiovasc Interv*. 2018;92(1):124-140. [CrossRef]
12. Aboyans V, Ricco JB, Bartelink MEL, et al. 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European Society for Vascular Surgery (ESVS): document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries Endorsed by: the European Stroke Organization (ESO) The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS). *Eur Heart J*. 2018;39(9):763-816. [CrossRef]
13. Steiner S, Schmidt A, Zeller T, et al. COMPARE: prospective, randomized, non-inferiority trial of high- vs. low-dose paclitaxel drug-coated balloons for femoropopliteal interventions. *Eur Heart J*. 2020;41(27):2541-2552. [CrossRef]
14. Baumhäkel M, Chkhetia S, Kindermann M. Treatment of femoro-popliteal lesions with scoring and drug-coated balloon angioplasty: 12-month results of the DCB-Trak registry. *Diagn Interv Radiol*. 2018;24(3):153-157. [CrossRef]
15. Bong TS, Yap CJ, Soon SX, Tang TY. Combination therapy using scoring and sirolimus drug-coated balloons during lower limb endovascular revascularization for chronic limb threatening ischaemia: A case series. *SAGE Open Med Case Rep*. 2022;10:2050313X221085859. [CrossRef]
16. Iida O, Urasawa K, Shibata Y, et al. Clinical safety and efficacy of rotational atherectomy in japanese patients with peripheral arterial disease presenting femoropopliteal lesions: the J-SUPREME and J-SUPREME II trials. *J Endovasc Ther*. 2022;29(2):240-247. [CrossRef]
17. Zeller T, Langhoff R, Rocha-Singh KJ, et al. Directional atherectomy followed by a paclitaxel-coated balloon to inhibit restenosis and maintain vessel patency: twelve-month results of the DEFINITIVE AR study. *Circ Cardiovasc Interv*. 2017;10(9):e004848. [CrossRef]
18. Katsanos K, Geisler BP, Garner AM, Zayed H, Cleveland T, Pietzsch JB. Economic analysis of endovascular drug-eluting treatments for femoropopliteal artery disease in the UK. *BMJ Open*. 2016;6(5):e011245. [CrossRef]