Comparison of Balloon Angioplasty and Stent Implantation for Femoropopliteal Disease According to Patient and Lesion Subgroup

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Background: Little is known about the superiority of balloon angioplasty vs. stent implantation for femoropopliteal (FP) lesions according to subgroup.

Methods and Results: This study involved 1,018 de novo (balloon angioplasty, n=462; stent implantation, n=556) and 114 in-stent restenosis (ISR) FP lesions (balloon angioplasty, n=69; stent implantation, n=45) treated with endovascular therapy. For de novo FP lesions, the 3-year primary patency rate was significantly better with stent implantation than with balloon angioplasty (61% vs. 69%, log-rank P=0.001), but it was similar for ISR FP lesions (40% vs. 43%, log-rank P=0.83). For de novo FP lesions, stent implantation was favorable in all subgroups except for female sex (hazard ratio [HR], 0.92; 95% CI: 0.65–1.31, P=0.66), critical limb ischemia (CLI; HR, 0.70; 95% CI: 0.46–1.06, P=0.10), calcified lesion (HR, 0.81; 95% CI: 0.46–1.39, P=0.44), and poor tibial run-off (HR, 0.86; 95% CI: 0.59–1.25, P=0.42) subgroups. No difference was found between the 2 treatment strategies for ISR FP lesions in the majority of subgroups. Stent implantation, however, was favorable in totally occluded ISR FP lesions (HR, 0.45; 95% CI: 0.21–1.01, P=0.05).

Conclusions: The primary patency rate in de novo FP lesions for the 2 treatment strategies was similar in the female, calcified lesion, CLI, and poor tibial run-off subgroups. Stent implantation was superior to balloon angioplasty for totally occluded ISR FP lesions.

Key Words: Balloon angioplasty; Endovascular therapy; Femoropopliteal disease; Peripheral artery disease; Stent implantation
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City Eastern Hospital between April 2007 and December 2016. A total of 1,018 de novo FP lesions (835 patients) and 114 in-stent restenosis (ISR) FP lesions (107 patients) were included in the present study. Complete written informed consent was obtained from all patients before the procedure, and subsequent data collection was performed to analyze anonymized data. The study protocol was in accordance with the Declaration of Helsinki and was

### Methods

**Subjects**

A retrospective review of hospital records was conducted to identify all patients who had successful balloon angioplasty and stent implantation for FP lesions at Yokohama City Eastern Hospital between April 2007 and December 2016. A total of 1,018 de novo FP lesions (835 patients) and 114 in-stent restenosis (ISR) FP lesions (107 patients) were included in the present study. Complete written informed consent was obtained from all patients before the procedure, and subsequent data collection was performed to analyze anonymized data. The study protocol was in accordance with the Declaration of Helsinki and was

### Table: Baseline Characteristics in De Novo FP Lesions

| Patient characteristics | Balloon angioplasty (462 lesions, 387 patients) | Stent implantation (556 lesions, 448 patients) | P-value |
|-------------------------|-----------------------------------------------|-----------------------------------------------|---------|
| Male                    | 231 (60)                                      | 309 (69)                                      | 0.005   |
| Age (years)             | 73±10                                         | 74±9                                          | 0.37    |
| Age >75 years           | 185 (48)                                      | 227 (51)                                      | 0.41    |
| Hypertension            | 299 (77)                                      | 351 (78)                                      | 0.71    |
| Hyperlipidemia          | 147 (38)                                      | 179 (40)                                      | 0.56    |
| Diabetes mellitus       | 211 (55)                                      | 230 (51)                                      | 0.34    |
| Hemodialysis            | 124 (32)                                      | 92 (21)                                       | <0.001  |
| Smoking                 | 34 (9)                                        | 59 (13)                                       | 0.05    |
| Previous PCI            | 113 (29)                                      | 138 (31)                                      | 0.61    |
| Previous cerebrovascular disease | 19 (5)                              | 14 (3)                                        | 0.19    |
| Critical limb ischemia  | 139 (36)                                      | 130 (29)                                      | 0.03    |
| Medication              |                                               |                                               |         |
| Aspirin                 | 285 (74)                                      | 385 (86)                                      | <0.001  |
| Thienopyridines         | 170 (44)                                      | 229 (51)                                      | 0.04    |
| Cilostazole             | 107 (28)                                      | 126 (28)                                      | 0.88    |
| Lesion characteristics  |                                               |                                               |         |
| Lesion length (mm)      | 90.5±68.7                                     | 133.5±78.6                                    | <0.001  |
| Lesion length >150 mm   | 104 (23)                                      | 249 (45)                                      | <0.001  |
| Chronic total occlusion | 117 (25)                                      | 263 (47)                                      | <0.001  |
| Calcified lesion        | 96 (21)                                       | 98 (18)                                       | 0.20    |
| TASC classification     |                                               |                                               |         |
| A                       | 156 (34)                                      | 144 (26)                                      | 0.006   |
| B                       | 155 (33)                                      | 129 (23)                                      | <0.001  |
| C                       | 81 (18)                                       | 132 (24)                                      | 0.02    |
| D                       | 70 (15)                                       | 151 (27)                                      | <0.001  |
| C or D                  | 151 (33)                                      | 283 (51)                                      | <0.001  |
| Involving common femoral artery | 30 (7)                          | 21 (4)                                        | 0.05    |
| Involving popliteal artery | 130 (28)                              | 43 (8)                                        | <0.001  |
| Poor tibial run-off     | 164 (36)                                      | 157 (28)                                      | 0.01    |
| Intervventional results |                                               |                                               |         |
| Stent Type              |                                               |                                               |         |
| SMART                   | –                                             | 355 (64)                                      | –       |
| Zilver 518              | –                                             | 43 (8)                                        | –       |
| Zilver PTX              | –                                             | 89 (16)                                       | –       |
| Misago                  | –                                             | 47 (9)                                        | –       |
| Others                  | –                                             | 16 (3)                                        | –       |
| No. stents              | –                                             | 1.8±0.9                                       | –       |
| Diameter of stent (mm)  | –                                             | 6.9±3.1                                       | –       |
| Length of stent (mm)    | –                                             | 155.7±99.0                                    | –       |
| POBA                    |                                               |                                               |         |
| Diameter of balloon (mm)| 4.5±0.9                                       | –                                              | –       |
| Length of balloon (mm)  | 73.1±51.1                                     | –                                              | –       |

Data given as mean±SD or n (%). FP, femoropopliteal; PCI, percutaneous coronary intervention; POBA, plain old balloon angioplasty; TASC, TransAtlantic InterSociety Consensus.
We performed these examinations when restenosis was considered as the cause of the symptom. We did not necessarily perform these examinations if the clinical course was favorable, at the operator’s discretion. Repeat revascularization was conducted based on the symptoms and on duplex ultrasound and angiography.

**Endpoint and Definitions**

The primary endpoint was the primary patency rate at 3 years, which was defined as freedom from >50% stenosis on angiography, or peak systolic velocity ratio >2.4 on duplex scan. The 3-year patency rate was calculated by excluding those who were lost to follow-up. The severity of FP lesions was evaluated using the TransAtlantic InterSociety Consensus (TASC) II classification. Severe calcification was defined for lesions with grade 3 or 4 in the Peripheral Arterial Calcium Scoring System. According to a previous report, poor tibial run-off was classified as run-off grade 0, which was defined as an antegrade flow impossible to reach the tibial vessels, or run-off grade 1, which was defined as infrapopliteal antegrade flow with delay. The types of ISR were classified according to the Tosaka classification: class 1, focal restenosis ≤5 cm; class 2, diffuse restenosis >5 cm; and class 3, total occlusion.

**Statistical Analysis**

All statistical analysis was conducted using SPSS version 19 (IBM-SPSS, Chicago, IL, USA). Categorical data are presented as n (%) and compared using Fisher’s exact test. Continuous variables with normal distributions are expressed as mean±SD, whereas non-normally distributed variables are presented as median (IQR). Continuous variables were compared using the unpaired t-test or non-parametric Mann-Whitney U-test. Kaplan-Meier analysis was performed to estimate the cumulative incidence of loss of primary patency, and the differences were evaluated using the log-rank test. We identified which lesion subgroups had better outcomes with stent implantation or balloon angioplasty using Cox proportional hazard analysis. All probability values were 2-sided, and P<0.05 was considered statistically significant.

**Results**

**Patient and Lesion Characteristics**

Table lists the baseline characteristics of 462 lesions (387 patients) treated with balloon angioplasty, and 556 lesions (448 patients) treated with stent implantation in de novo FP lesions. Patients treated with balloon angioplasty were predominantly female and had a higher prevalence of hemodialysis and critical limb ischemia (CLI). Lesion length was significantly longer; and severe lesion background, such as chronic total occlusion and TASC classification C or D, was significantly more prevalent in lesions treated with stent implantation. The rate of poor tibial run-off was significantly higher in lesions treated with balloon angioplasty.

The baseline characteristics of 69 lesions (64 patients) treated with balloon angioplasty and 45 lesions (43 patients) treated with stent implantation in ISR FP lesions are described in Supplementary Table 1. No significant difference was found in patient demographics and lesion severity at initial stenting between the 2 groups. With regard to the type of restenosis, however, classes 1 and 2 were more prevalent in lesions treated with balloon angioplasty, and class 3 was more prevalent in lesions treated...
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Outcome Measures
The median follow-up period of de novo FP lesions was 20.6 months (IQR, 7.8–35.3 months). The primary patency rates at 1, 2, and 3 years were 72%, 67%, and 61%, respectively, for lesions treated with balloon angioplasty, and 84%, 74%, and 69%, respectively, for lesions treated with stent implantation (log-rank P=0.001; Figure 1). Stent implantation was associated with improved primary patency (hazard ratio [HR], 0.68; 95% CI: 0.54–0.86, P=0.001), and this remained significant after adjusting for age >75 years, gender, diabetes, CLI, calcification, poor tibial run-off, chronic total occlusion, lesion length >150 mm, and TASC classification C or D (HR, 0.61; 95% CI: 0.47–0.79, P=0.0002) in de novo FP lesions. On subgroup analysis, stent implantation was not associated with better primary patency rate in female patients (HR, 0.92; 95% CI: 0.65–

Figure 2. Cox proportional hazard modeling of the subgroups associated with better primary patency rate for de novo femoropopliteal lesions treated with balloon angioplasty or stent implantation. Calc, calcified lesions; CLI, critical limb ischemia; CTO, chronic total occlusion; DM, diabetes mellitus; HD, hemodialysis; HL, hyperlipidemia; HT, hypertension; TASC, TransAtlantic InterSociety Consensus.

Figure 3. Primary patency rate at 1, 2, and 3 years for de novo femoropopliteal lesions treated with balloon angioplasty and stent implantation in (A) female and (B) male patients.
months (IQR, 6.6–35.3 months). The primary patency rate at 1, 2, and 3 years was similar for lesions treated with balloon angioplasty (55%, 44%, and 40%, respectively) and stent implantation (61%, 47%, and 43%, respectively; log-rank P=0.83; Figure 5). On subgroup analysis stent implantation was associated with a better primary patency rate than balloon angioplasty in the subgroup of class 3 lesions (HR, 1.31; 95% CI: 0.67–2.55, P=0.66), or in the CLI (HR, 0.70; 95% CI: 0.46–1.06, P=0.10), calcified lesions (HR, 0.81; 95% CI: 0.46–1.39, P=0.44), and poor tibial run-off groups (HR, 0.86; 95% CI: 0.59–1.25, P=0.42; Figure 2). The primary patency rate at 3 years was similar for lesions treated with balloon angioplasty and stent implantation in female patients (60% vs. 56%, log-rank P=0.66; Figure 3A). The rate at 3 years, however, was significantly higher for lesions treated with stent implantation than balloon angioplasty in male patients (62% vs. 75%, log-rank P=0.0007; Figure 3B). The primary patency rate at 3 years was significantly higher for non-calcified lesions treated with stent implantation than balloon angioplasty (61% vs. 70%, log-rank P=0.002; Figure 4A), but it was not different for calcified lesions between the 2 groups (62% vs. 65%, log-rank P=0.61; Figure 4B). These results in the subgroup analyses remained even after adjusting for important covariates (Supplementary Table 2).

The median follow-up period of ISR FP lesions was 11.6 months (IQR, 6.6–35.3 months). The primary patency rate at 1, 2, and 3 years was similar for lesions treated with balloon angioplasty (55%, 44%, and 40%, respectively) and stent implantation (61%, 47%, and 43%, respectively; log-rank P=0.83; Figure 5). On subgroup analysis stent implantation was associated with a better primary patency rate than balloon angioplasty in the subgroup of class 3 lesions (HR, 1.31; 95% CI: 0.67–2.55, P=0.66), or in the CLI (HR, 0.70; 95% CI: 0.46–1.06, P=0.10), calcified lesions (HR, 0.81; 95% CI: 0.46–1.39, P=0.44), and poor tibial run-off groups (HR, 0.86; 95% CI: 0.59–1.25, P=0.42; Figure 2). The primary patency rate at 3 years was similar for lesions treated with balloon angioplasty and stent implantation in female patients (60% vs. 56%, log-rank P=0.66; Figure 3A). The rate at 3 years, however, was significantly higher for lesions treated with stent implantation than balloon angioplasty in male patients (62% vs. 75%, log-rank P=0.0007; Figure 3B). The primary patency rate at 3 years was significantly higher for non-calcified lesions treated with stent implantation than balloon angioplasty (61% vs. 70%, log-rank P=0.002; Figure 4A), but it was not different for calcified lesions between the 2 groups (62% vs. 65%, log-rank P=0.61; Figure 4B). These results in the subgroup analyses remained even after adjusting for important covariates (Supplementary Table 2).

The median follow-up period of ISR FP lesions was 11.6
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(HR, 0.45; 95% CI: 0.21–1.01, P=0.05; Figure 6). Figure 7 shows the difference in loss of primary patency at 3 years according to ISR type. Restenosis rate was similar for lesions treated with balloon angioplasty and stent implantation in the overall group, and in class 1 or 2 groups, but it tended to be higher for those treated with balloon angioplasty in class 3 (79% vs. 52%, P=0.09).

**Discussion**

The present study has found the following: stent implantation for de novo FP lesions was not associated with improvement in primary patency rate compared with balloon angioplasty in the subgroups of female sex, CLI, calcified lesion, and poor tibial run-off. The efficacy of stent implantation for ISR FP lesions was limited to class 3 ISR FP lesions only.

EVT has a higher incidence of target lesion revascularization (TLR) in female patients than in male patients. Female patients are expected to have smaller FP vessels than male patients. Kamioka et al showed that the cumulative 3-year incidence of primary patency in FP lesions with a vessel size ≤4.0mm is significantly higher in balloon angioplasty than in stent implantation (53.8% vs. 34.2%, P=0.002). In addition, stent implantation is a predictor of restenosis for small vessel FP lesions (HR, 1.68; 95% CI: 1.15–2.41, P=0.01). Implantation of metallic stent inside a small vessel occupies the lumen area and sometimes leads to insufficient stent area. Moreover, the impact of underexpansion on restenosis in small vessel lesions is greater than in large vessel lesions. Therefore, stent implantation may not be a reasonable strategy for small vessel FP lesions, and the concept of “leave nothing behind” is more reasonable. Laird et al showed that primary patency at 24 months in female patients treated with DCB was significantly higher than in those treated with conventional balloon angioplasty (76.7% vs. 42.3%, P=0.001). To improve the results of EVT for small vessel FP lesions, advances in DCB technology are essential.

Severely calcified FP lesions remain a challenging subset to treat by EVT. Stent implantation for lesions with severe calcification is associated with stent underexpansion and loss of primary patency. Tepe et al reported that severe calcification is one of the predictors of late lumen loss after EVT with DCB. Lesion preparation using atherectomy devices before both stent implantation and DCB may be a good option for EVT of severely calcified FP lesions. Zeller et al found that directional atherectomy using the SilverHawk or TurboHawk devices (Medtronic, formerly Covidien/ev3, Plymouth, MN, USA) before DCB increases the technical success rate (89.6% vs. 64.2%, P=0.004) and decreases flow-limiting dissection (2.1% vs. 18.5%, P=0.01) compared with DCB alone. Foley et al reported that orbital atherectomy before DCB is associated with reduced bailout stenting compared with DCB alone (18% vs. 39%, P=0.01). Little is known, however, about whether the use of atherectomy device prior to DCB is associated with improvement in clinical outcomes including long-term primary patency, reduction of TLR, and freedom from major adverse events. In contrast, Maehara et al, using IVUS, showed that the JETSTREAM atherectomy system (Boston Scientific, Marlborough, MA, USA) modifies superficial calcium and that adjunctive balloon angioplasty after modification of calcium leads to further lumen increase without major complications. Thus, investigating the type of calcium to be modified and the approach to be used with atherectomy devices is important to achieve maximum efficacy of atherectomy devices and prove clinical utility. Therefore, more detailed studies focusing on intravascular imaging after using atherectomy devices and clinical outcomes are needed.

Poor tibial run-off is known to be a cause of patency loss in FP interventions. Whether stent implantation or balloon angioplasty is better for poor tibial run-off, however, is not clear. In the present study stent implantation was not superior to balloon angioplasty in maintaining primary patency in CLI and in the case of poor tibial run-off. Long-term patency after FP stent implantation is not expected in patients with poor outflow status. Therefore, DCB is also a reasonable option for FP lesions with CLI.
or poor tibial run-off, but studies on this issue are limited. The optimal EVT strategy for ISR FP lesions remains unclear. In the present study, additional stent implantation was not effective in reducing repeat restenosis compared with balloon angioplasty, except in subgroup class 3 ISR FP lesions. This is because the incidence of repeat restenosis with balloon angioplasty for class 3 ISR FP lesions was very much higher than that for other types of ISR FP lesions. We considered that class 3 ISR FP lesions have a large amount of plaque burden inside the stent. Therefore, balloon angioplasty could not obtain sufficient lumen area due to recoil and residual stenosis, compared with non-occluded patterns of ISR FP lesions. Although DCB is a good strategy for ISR FP lesions, Grott et al found that using DCB did not improve the repeat TLR rate at 3 years compared with conventional balloon angioplasty (40% vs. 43%, P=0.8). We considered that one of the treatment options for ISR FP lesions, such as calcified lesions, is the use of atherectomy devices. Laser atherectomy can reduce plaque burden inside the stent, leading to reduced repeat TLR for ISR FP lesions. Further research is necessary to investigate this issue in real-world practice.

Study Limitations
This study had several limitations. First, it was a retrospective non-randomized analysis from a single-center database with a relatively small sample size; therefore, selection bias may exist. In addition, the treatment strategy was dependent on operator discretion. Second, the results of DCB and stent implantation could not be compared because DCB was still not available in Japan during the study period. Although several studies have compared the efficacy of standard balloon and DCB for FP lesions, little is known about the utility of DCB vs. stent implantation. This study will help in determining the appropriate population for use of DCB because balloon angioplasty is a basic mechanism of DCB. Finally, we could not use new-generation stents, such as the Supera stent, which has polymer coating, because they were still not available in Japan during the study period. Further research is needed to examine whether similar results are obtained using the new-generation stents.

Conclusions
Stent implantation for de novo FP lesions had favorable outcomes compared with balloon angioplasty. The efficacy of stent implantation over balloon angioplasty, however, was not observed in female patients or in the case of calcified lesions, CLI, and poor tibial run-off. The clinical effect of balloon angioplasty and additional stent implantation for ISR FP lesions was similar, except for total occlusion of ISR. The optimal indication of DCB should be investigated in further studies to improve the outcomes of FP lesions.

Disclosures
The authors declare no conflicts of interest.

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**Supplementary Files**

Please find supplementary file(s);

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