The official journal of the Japan Atherosclerosis Society and
the Asian Pacific Society of Atherosclerosis and Vascular Diseases

Original Article

J Atheroscler Thromb, 2019; 26: 847-855. http://doi.org/10.5551/jat.47399

One-Year Clinical Outcomes following Implantation of Innova™ Self-Expanding Nitinol Stents in Patients with Peripheral Artery Diseases Presenting Femoropopliteal Artery Lesions

Takuya Tsujimura[1], Mitsuyoshi Takahara[2], Osamu Iida[1], Seiichi Hiramori[3], Naoki Hayakawa[4], Eiji Karashima[5], Takashi Miura[6], Masanori Teramura[7], Kei Ichihashi[7], Tai Kojima[8], Hideaki Aihara[9], Terutoshi Yamaoka[10], Masahiko Fujihara[11], Atsushi Tosaka[12], Tatsuki Doijiri[13], Toshiaki Mano[1] and Yoshimitsu Soga[3]

[1]Cardiovascular Center, Kansai Rosai Hospital, Amagasaki, Japan
[2]Department of Metabolic Medicine, Osaka University Graduate School of Medicine, Suita, Japan
[3]Department of Cardiology, Kokura Memorial Hospital, Kitakyushu, Japan
[4]Department of Cardiology, Asahi General Hospital, Chiba, Japan
[5]Department of Cardiology, Shimonoseki Central Hospital, Shimonoseki, Japan
[6]Department of Cardiovascular Medicine, Shinshu University School of Medicine, Matsumoto, Japan
[7]Department of Cardiovascular Medicine, Ichinomiya Nishi Hospital, Ichinomiya, Japan
[8]Department of Cardiology, Gifu Prefectural General Medical Center, Gifu, Japan
[9]Department of Cardiology, Tsukuba Medical Center Hospital, Tsukuba, Japan
[10]Department of Vascular Surgery, Matsuyama Red Cross Hospital, Matsuyama, Japan
[11]Department of Cardiology, Kishiwada Tokushukai Hospital, Kishiwada, Japan
[12]Department of Cardiology, Kawakita General Hospital, Tokyo, Japan
[13]Department of Cardiology, Yamato Seiwa Hospital, Yamato, Japan

Aim: Although the Innova™ self-expanding nitinol stent (Boston Scientific, Marlborough, MA) exhibits acceptable performance in long-term safety and efficacy when used for the treatment of femoropopliteal (FP) lesions, clinical outcomes following its implantation have not been systematically studied in real-world settings. We investigated the one-year clinical outcomes after implantation of Innova™ self-expanding nitinol stents for the treatment of FP lesions in real-world settings.

Methods: In this multicenter study, 481 lesions in 453 consecutive patients with peripheral artery disease (PAD) (74 ± 9 years; male, 70%; diabetes mellitus, 61%; dialysis, 27%; critical limb ischemia, 37%) who underwent endovascular therapy with the implantation of Innova™ self-expanding nitinol stents for FP lesions were analyzed from February 2016 to April 2017. The primary endpoint was one-year restenosis, whereas the secondary endpoints included one-year major adverse limb events and predictors for one-year restenosis.

Results: The mean lesion length was 18 ± 10 cm. One-year restenosis and major adverse limb event rates were 36% and 18%, respectively. Multivariate analysis revealed that the presence of diabetes mellitus (odds ratio [OR]: 1.83; 95% confidence interval [CI]: 1.07–3.13), distal reference vessel diameter (OR: 1.86; 95% CI: 1.09–3.16), spot stenting (OR: 2.27; 95% CI: 1.27–4.06), and lack of one-year cilostazol treatment (OR: 0.58; 95% CI: 0.33–1.00) were independent risk factors for one-year restenosis.

Conclusion: The current study demonstrated one-year clinical outcomes after Innova™ self-expanding nitinol stent placement for the treatment of FP lesions, including challenging cases in real-world settings.

Key words: Peripheral artery disease, Endovascular therapy, Innova™ self-expanding stent

Address for correspondence: Takuya Tsujimura, Kansai Rosai Hospital Cardiovascular Center, 3-1-69 Inabaso Amagasaki, Hyogo 660-8511, Japan
E-mail: t.tsujimura0110@gmail.com

Received: October 5, 2018 Accepted for publication: January 7, 2019

Introduction

Endovascular therapy (EVT) is widely used for the treatment of symptomatic lower extremity ischemia due to technological advances and is now commonly recommended in the latest guidelines[1-3]. Although EVT is an effective therapeutic option for femoropopliteal (FP) lesions, traditional percutaneous transluminal angioplasty has reportedly demonstrated uniformly poor results as the primary treatment for FP lesions[4-7], whereas the patency rate of the FP artery has reportedly improved through the use of self-expanding nitinol stents[8-10].

The Innova™ self-expanding nitinol stent (Boston Scientific, Marlborough, MA, USA) has been available for the treatment of FP lesions since February 2016 in Japan. The SuperNOVA study, the first human trial of the Innova™ self-expanding nitinol stent, demonstrated acceptable clinical outcomes in the treatment of FP lesions[11]. However, the disease severity of the trial population seemed less severe than that of the real-world population observed in clinical practice. To date, clinical outcomes following Innova™ implantation for the treatment of FP lesions, including challenging cases, remain to be systematically studied in real-world settings. Therefore, we examined the one-year clinical outcomes following Innova™ implantation for the treatment of FP lesions in patients with peripheral arterial disease (PAD) in real-world settings.

Methods

Study Population

We analyzed a total of 481 lesions in 453 consecutive patients implanted with Innova™ stents for the treatment of FP artery stenosis or occlusion from February 2016 to April 2017 at 30 centers in Japan. One-year clinical outcomes, including one-year restenosis, were routinely checked in the clinics at the participating centers. Patients with symptomatic PAD were screened by noninvasive tests to detect limb ischemia and the presence of FP lesions. All patients had symptomatic FP lesions (Rutherford 1–6) despite exercise therapy and appropriate medications. The anatomical inclusion criteria were stenosis of ≥ 50% or occlusion of the FP artery as determined by angiography. The study was performed in accordance with the Declaration of Helsinki and was approved by the ethics committee of each center that registered patients. In accordance with the Ethical Guidelines for Medical and Health Research Involving Human Subjects in Japan, the current study, performed with the secondary use of data from medical records, was considered exempt from informed consent. The relevant information regarding the study was, instead, open to the public.

Endovascular Therapy

The decision of Innova™ implantation was left to the discretion of physicians. All procedures were performed under local anesthesia. For EVT, a 6-F sheath was inserted into the femoral artery mostly with an ipsilateral or contralateral approach. After a 5,000 U heparin infusion, 0.035- or 0.014-inch guidewires were used to cross the lesions. The lesions were expanded using an optimal balloon according to angiographic examination of the reference vessel. Prior to stent implantation, the guidewire was replaced with a 0.035-inch guidewire that was compatible with the stent delivery system. Regarding the stenting strategy, spot stenting or full covered stenting were chosen by the operators' discretion. Although the entire lesion length was covered in the full covered stenting group, the entire lesion length was not covered with stents and stents were implanted only in the lesions that acute results after balloon dilation were insufficient due to residual stenosis or dissectionin the spot stenting group. The stent size was chosen to be 1 or 2 mm larger than the reference vessel diameter in accordance with the instructions provided by the manufacturer for the use of Innova™ self-expanding stent. Although we decided stent sizes based on reference vessel diameters measured by intravascular ultrasound (IVUS) in patients with IVUS use (68%), we selected stent sizes based on reference vessel diameters measured by quantitative vessel angiography (QVA) in those without IVUS use. A final post-dilatation was performed with a balloon with a size equivalent to the distal vessel diameter. Balloon pre- and post-dilatation were considered to be necessary, according to the physician's judgment. Antiplatelet and anticoagulant regimens were used according to the physician's discretion based on the patient's condition.

Follow-Up

Patients who underwent EVT for the treatment of FP lesions were asked to routinely visit the participating centers 1, 3, 6, and 12 months following EVT. At each visit, ischemic symptoms and the ankle-brachial index were evaluated, and duplex ultrasonography (DUS) was routinely conducted to evaluate patency. Angiography was performed by each doctor's discretion. Repeated revascularization was performed based on clinical symptoms and findings on DUS or angiography.

Endpoints

The primary endpoint was one-year restenosis

assessed by DUS or follow-up angiography, with a tolerance of ±2 months. Restenosis was defined as the recurrence of ≥ 50% diameter stenosis determined by angiography or a peak systolic velocity ratio >2.4 determined by DUS. Requirement of any re-intervention or major amputation within one year was included in restenosis. Secondary endpoints included one-year major adverse limb event (MALE), thrombotic occlusion, stent fracture, perioperative major adverse event (MAE), post-procedural residual stenosis, edge dissection, and stent elongation. One-year MALE was defined as major amputation or any re-intervention, including both surgical or endovascular re-intervention, within one year, whereas MAE was defined as 30-day all-cause mortality and MALE. The in-stent restenosis (ISR) following Innova™ implantation was classified into three classes by visual estimate on angiography: class I, the focal (≤ 50 mm in length) ISR group, included lesions at the stent body, the stent edge, or a combination of these sites; class II, the diffuse (>50 mm in length) ISR group, included lesions at the stent body and the stent edge; and class III, the totally occluded ISR group[12].

Statistical Analysis

Data are represented as the mean and standard deviation for continuous variables or as percentages for dichotomous variables, unless otherwise mentioned. A p of <0.05 was considered statistically significant. The incidence of restenosis at one year in the overall population was calculated as $P_{MALE} + (1 - P_{MALE}) \times P_{Restenosis}$, where P_{MALE} and $P_{Restenosis}$ indicate the one-year MALE incidence rate in the overall population and one-year restenosis prevalence in the MALE-free subgroup, respectively. Since some patients completed the one-year follow-up without MALE but failed to undergo patency assessment at 12±2 months, we estimated $P_{Restenosis}$ based on the hypothesis that cases with missing data on patency are subject to the same risk as the observed cases, such as by Kaplan–Meier estimation. Therefore, $P_{Restenosis}$ was calculated to be equal to the prevalence of restenosis in the population that completed the one-year follow-up without MALE and underwent patency assessment at 12±2 months. The one-year incidence rate of MALE (i.e., P_{MALE}), as well as that of thrombotic occlusion, was estimated using the Kaplan–Meier method. The 95% confidence intervals (CIs) of the endpoints were estimated by 10,000-times bootstrap resampling. The association of baseline characteristics with restenosis risk was assessed using the logistic regression model. Independent associations were explored by the multivariate logistic regression model, in which explanatory variables that were statistically significant in the univariate model were entered. All statistical analyses were performed by R version 3.1.0 (R Core Team, Vienna, Austria).

Results

Patient and Lesion Characteristics

Baseline characteristics of the study population are presented in **Table 1**. One-third of patients presented with critical limb ischemia. The mean lesion length was 18±10 cm, and more than 50% patients were classified as TransAtlantic Inter-Society Consensus (TASC) II class C/D. Among 481 limbs of 453 patients, 96 (20%) did not exhibit MALE before the one-year assessment. Of the remaining cases, 63 limbs exhibited MALE within one year, whereas 322 were MALE-free. Of the 322 MALE-free lesions, 247 limbs (77%) underwent patency assessment at 12±2 months, whereas 75 did not.

One-Year Clinical Outcomes

Fig. 1 shows the post-procedural, perioperative, and one-year clinical outcomes. The one-year incidence of restenosis in the overall population was estimated to be 36% (95% CI: 31%–42%), whereas one-year MALE was observed in 18% (95% CI: 14%–22%) patients, indicating that MALE occurred in approximately half of the cases of patients with restenosis. Regarding ISR classification, 42% were class I (focal ISR), 28% class II (diffuse ISR), and 30% class III (totally occluded ISR).

Table 2 represents the logistic regression analysis of predictors for one-year restenosis. The restenosis risk was not significantly different between patients with critical limb ischemia and those with intermittent claudication (odds ratio: 1.18 [95% CI: 0.73–1.90]; $P=0.49$); the estimated one-year restenosis rate was 37% (95% CI: 28%–46%) and 36% (95% CI: 30%–42%), respectively. The presence of diabetes mellitus, small distal reference vessel diameter, spot stenting, and lack of one-year cilostazol treatment were identified as independent risk factors for one-year restenosis. The accumulation of these four risk factors was associated with an increased risk of one-year restenosis (**Fig. 2**).

Discussion

The current study demonstrated one-year clinical outcomes following Innova™ implantation for the treatment for FP lesions, including challenging cases as observed in clinical practice in real-world settings. The one-year incidence of restenosis in the overall population was 36%, whereas one-year MALE was

Table 1. Baseline characteristics of study population

	Overall population	Patients with diabetes mellitus	Patients without diabetes mellitus	*P* value (Patients with versus without diabetes mellitus)
n	481	295	186	
Male sex	336 (70%)	208 (71%)	128 (69%)	0.76
Age	74 ± 9	73 ± 9	76 ± 9	0.006
Non-ambulatory status	96 (20%)	62 (21%)	34 (18%)	0.48
Diabetes mellitus	295 (61%)	295 (100%)	0 (0%)	< 0.001
Regular dialysis	129 (27%)	85 (29%)	44 (24%)	0.25
Critical limb ischemia	180 (37%)	120 (41%)	60 (32%)	0.067
TASC II classification				0.066
Class A	83 (17%)	56 (19%)	27 (15%)	
Class B	123 (26%)	73 (25%)	50 (27%)	
Class C	135 (28%)	91 (31%)	44 (24%)	
Class D	140 (29%)	75 (25%)	65 (35%)	
Distal reference vessel diameter (mm)	5.0 ± 1.0	4.9 ± 1.0	5.2 ± 0.9	0.002
< 5 mm	195 (44%)	126 (47%)	69 (40%)	0.17
(missing data)	38 (8%)	25 (8%)	13 (7%)	0.61
Chronic total occlusion	259 (54%)	152 (52%)	107 (58%)	0.22
PACSS classification				0.03
Grade 0	134 (28%)	73 (25%)	61 (33%)	
Grade 1	106 (22%)	65 (22%)	41 (22%)	
Grade 2	67 (14%)	41 (14%)	26 (14%)	
Grade 3	56 (12%)	36 (12%)	20 (11%)	
Grade 4	118 (25%)	80 (27%)	38 (20%)	
In-stent restenosis	25 (5%)	17 (6%)	8 (4%)	0.53
Lesion length (cm)	18 ± 10	18 ± 10	17 ± 10	0.51
≥ 25 cm	140 (29%)	92 (31%)	48 (26%)	0.22
Pre-dilatation	461 (96%)	283 (96%)	178 (96%)	1.00
Spot stenting	111 (23%)	68 (23%)	43 (23%)	1.00
(missing data)	1 (0%)	1 (0%)	0 (0%)	1.00
Post-dilatation	399 (83%)	250 (85%)	149 (80%)	0.21
Intravascular ultrasound use	328 (68%)	200 (68%)	128 (69%)	0.84
1-year dual antiplatelet therapy	249 (52%)	158 (54%)	91 (49%)	0.35
1-year cilostazol treatment	170 (35%)	103 (35%)	67 (36%)	0.84

observed in 18% patients. The presence of diabetes mellitus, a small distal reference vessel diameter, spot stenting, and the lack of cilostazol administration were identified as independent risk factors for one-year restenosis. The one-year restenosis rate in lesions without these risk factors was 12%, whereas it was 53% in those with ≥ 3 risk factors. To the best of our knowledge, this is the first study to investigate clinical outcomes and associated risk factors following Innova™ implantation for the treatment of FP lesions in a real-world setting.

EVT is a widely used techniqueand has been recognized as a common treatment for PAD[1-3]. The patency rate of the FP artery has reportedly improved through the use of the self-expanding nitinol stent, and the clinical outcome and patency rate of the nitinol stent has already been reported[8-10, 13]. The Innova™ stent became available in 2016 as a new self-expanding nitinol stent for the treatment of FP lesions in Japan. The Innova™ stent has a hybrid cell structure comprising closed-cell ends for deployment stability and uniformity and an open-cell center for flexibility and fracture resistance. Furthermore, we expect more precise positioning during stent implantation due to tantalum markers of the stent edge for improved visibility and the non-flared stent edge for reduced jumping. Owing to its structure, the Innova™ stent is expected to prevent vessel collapse and provide stability and a radial force for treatment of complex FP lesions. In the current study, TASC C/D and severely calcified lesions, which have been generally reported as risk factors for loss of patency in previ-

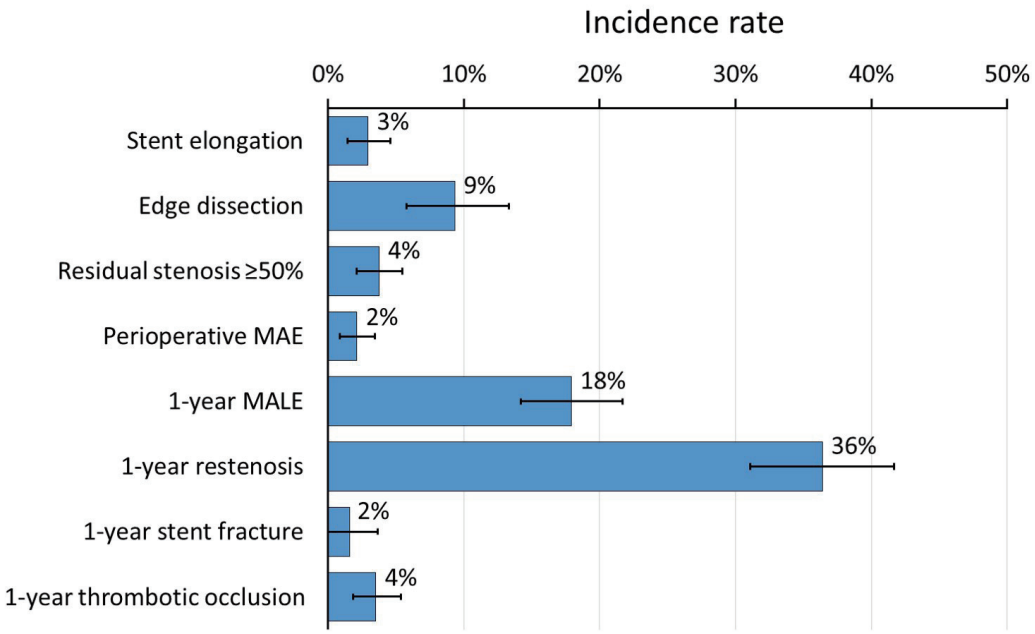

Fig. 1. Post-procedural, perioperative, and one-year clinical outcomes
Error bars represent 95% confidence intervals.

Table 2. Risk factors associated with 1-year restenosis

	Unadjusted OR	Adjusted OR
Male sex	0.49 [0.30-0.81]*	0.73 [0.41-1.30]
Age (per 10 years)	1.05 [0.81-1.36]	---
Nonambulatory status	1.35 [0.72-2.52]	---
Diabetes mellitus	1.81 [1.12-2.91]*	1.83 [1.07-3.13]*
Regular dialysis	0.97 [0.58-1.61]	---
Critical limb ischemia	1.18 [0.73-1.90]	---
TASC II classification (vs. class A)	1.00 (Ref)	---
Class B	0.90 [0.43-1.85]	---
Class C	0.93 [0.46-1.89]	---
Class D	1.53 [0.77-3.05]	---
Distal reference vessel diameter < 5 mm	2.36 [1.45-3.85]*	1.86 [1.09-3.16]*
Chronic total occlusion	1.16 [0.74-1.83]	---
PACSS classification	1.04 [0.90-1.20]	---
In-stent restenosis	3.09 [1.03-9.28]*	2.51 [0.73-8.64]
Lesion length ≥ 25 cm	1.98 [1.21-3.22]*	1.75 [1.00-3.09]
Predilatation	0.91 [0.31-2.68]	---
Spot stenting	2.74 [1.60-4.68]*	2.27 [1.27-4.06]*
Postdilatation	0.97 [0.53-1.79]	---
Intravascular ultrasound use	0.63 [0.38-1.03]	---
One-year dual antiplatelet therapy	1.41 [0.90-2.22]	---
One-year cilostazol treatment	0.62 [0.38-1.00]*	0.58 [0.33-1.00]*

Data are odds ratios and their 95% confidence intervals. Asterisks indicate $p < 0.05$.

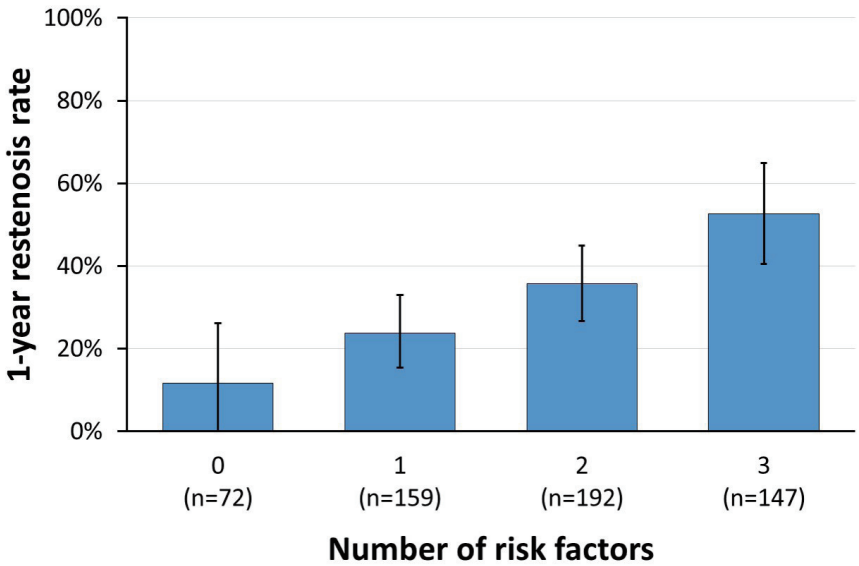

Fig.2. Increased one-year restenosis risk in subgroups with accumulated risk factors

The risk factors were as follows: 1) diabetes mellitus, 2) distal reference vessel diameter <5 mm, 3) spot stenting, and 4) lack of one-year cilostazol administration (see Table 2). Error bars represent 95% confidence intervals.

ous reports[14-16], were not found to be predictive factors for one-year restenosis. Based on these results, the Innova™ stent can be considered to be suitable for complicated cases.

The SuperNOVA study reported clinical outcome results following Innova™ stent implantation; the primary patency rate at one year was 66.4% for the full stent length matrix[11]. Compared to those in the SuperNOVA study, the frequencies of critical limb ischemia, diabetes mellitus, maintenance dialysis, TASC II class C/D lesions, and chronic total occlusion lesions were higher, and the lesion length was longer in the current study. Given that the patient characteristics and lesion characteristics were worse in this study than in the SuperNOVA study, the one-year incidence rate of restenosis in this study can be considered acceptable. Furthermore, previous reports regarding other self-expanding nitinol stents for the treatment of FP lesions showed that primary patency rates at one yearC after stent implantation were 81%–82% for S.M.A.R.T. stent™, 74% for Luminexx stent™, 70%–87% for Misago stent™, and 81% for Lifestent™ [16-21]. In this study, the incidence of restenosis following implantation of the Innova™ stent was 36% at one year, which was worse than the incidence rates that have been reported following the use of other self-expanding nitinol stents for the treatment of FP lesions. This discrepancy could be attributed to the severity of the condition of the current study population. The current study included more complex lesions to reflect the cases observed in real-world settings, which may have led to a lower patency rate.

Risk analysis revealed that diabetes mellitus was independently associated with future restenosis. This finding was consistent with that of previous studies. There is a general agreement that diabetes mellitus is a significant risk factor for the development of PAD[22]. Furthermore, diabetes mellitus was considered as one of the significant risk factors for loss of patency after FP intervention[23, 24]. The current study demonstrated that diabetes mellitus was similarly a risk factor for restenosis following Innova™ stent implantation for the treatment of FP lesions. Thus, it is necessary to closely follow-up patients with PAD suffering from diabetes mellitus for a long term.

The distal reference vessel diameter was another independent predictor of restenosis. The findings of the study indicate that a smaller vessel would be subject to poorer stent patency. Previous reports regarding the relationship between clinical outcomes and vessel size in EVT for the treatment of FP lesions have reported that a small reference vessel diameter, especially a vessel diameter ≤ 4 mm, is associated with poor EVT outcomes[25]. One possible explanation for this observation is that the small reference vessel diameter itself is related to poor EVT outcomes, and another explanation is that a small vessel diameter relative to the stent diameter exacerbates EVT outcomes

due to increased intramural stress from the stent, causing early restenosis by triggering neointimal hyperplasia. Therefore, if possible, it may be beneficial to perform balloon angioplasty and avoid Innova™ stent implantations for the treatment of FP lesions with a small reference vessel diameter.

Spot stenting was also identified as one of the risk factors for restenosis in the current study; however, the reason was unclear. Previous reports have revealed that primary implantation of self-expanding nitinol stents in the FP artery, especially in moderate-length lesions, is associated with better acute angiographic results and better patency than those with seen balloon angioplasty alone[8, 26]. Therefore, it was speculated that spot stenting leads to worse clinical outcomes than full covered stenting because the lesions with only balloon angioplasty in the spot stenting group might occur restenosis more frequently.

The other risk factor for restenosis was the lack of one-year cilostazol treatment. This result was similar to that in reported by previous studies[27-30]. Based on this result, it may be beneficial to continue cilostazol treatment after Innova™ stent implantation for as long as possible.

Study Limitations

The present study had several limitations. First, the current study included only Japanese patients, and thus, the results should be confirmed in other ethnic groups. Second, this study was not designed to compare the efficacy of Innova™ implantation with that of other treatments. It remains to be studied whether Innova™ implantation is superior to other treatments in real-world settings. Third, the observation period was only one year, and the treatment results thereafter in the chronic phase are unknown. Fourth, the assessment of restenosis by angiography and DUS was not conducted by the core laboratory. Fifth, although spot stenting was a risk factor for restenosis, the detail of the methods used for spot stenting are ambiguous. The stenting strategy was chosen by the operators' discretion. Further investigation is warranted.

Conclusion

The current study demonstrated one-year clinical outcomes following Innova™ self-expanding nitinol stent implantation for the treatment of FP lesions, including challenging cases in real-world settings. The Innova™ stent system demonstrated acceptable clinical outcomes.

Acknowledgments

The authors acknowledge the expertise of Seiichi Hiramori of Kokura Memorial Hospital, Koji Hozawa of New Tokyo Hospital, Daizo Kawasaki of Morinomiya Hospital, Keisuke Hirano of Saiseikai Yokohama City Eastern Hospital, Kazushi Urasawa of Tokeidai Memorial Hospital, Yasutaka Tamauchi of Takatsu General Hospital, Taketsugu Tsuchiya of Kanazawa Medical University Hospital, Yusuke Miyashita of Nagano Red Cross Hospital, Terutoshi Yamaoka of Matsuyama Red Cross Hospital, Kenji Suzuki of Tokyo Saiseikai Central Hospital, Toru Mazaki of Kobe Central Hospital, Nobuhiro Suematsu of Saiseikai Fukuoka General Hospital, Yoshiaki Shintani of Shin-Koga Hospital, Masahiko Fujihara of Kishiwada Tokushukai Hospital, Atsushi Tosaka of Kawakita General Hospital, Tatsuki Doijiri of Yamato Seiwa Hospital, Takashi Miura of Shinshu University School of Medicine, Masahito Taniguchi of Fukuyama Cardiovascular Hospital, Tai Kojima of Gifu University Graduate School of Medicine, Jun Nakazato of Okinawa Chubu Hospital, Hideaki Aihara of Tsukuba Medical Center Hospital, Souichiro Enomoto of Tenri Hospital, Masahiko Noguchi of Tokyo Bay Urayasu Ichikawa Medical Center, Naotaka Murata of Tokyo Medical University Hospital, Yohei Kobayashi of Osaka Red Cross Hospital, Masanori Teramura of Ichinomiya Nishi Hospital, Kei Ichihashi of Ichinomiya Nishi Hospital, Eiji Karashima of Shimonoseki City Hospital, Hideo Tokuyama of Kawaguchi Heart Respiratory Hospital and Naoki Hayakawa of Asahi General Hospital in performing the catheterization procedures and data collection.

Disclosures

The authors declare no conflicts of interest associated with this manuscript.

References

1) Aboyans V, Ricco JB, Bartelink MEL, Björck M, Brodmann M, Cohnert T, Collet JP, Czerny M, De Carlo M, Debus S, Espinola-Klein C, Kahan T, Kownator S, Mazzolai L, Naylor AR, Roffi M, Röther J, Sprynger M, Tendera M, Tepe G, Venermo M, Vlachopoulos C, Desormais I. 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 arteriesEndorsed 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: 763-816
2) Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, Fleisher LA, Fowkes FG, Hamburg NM, Kinlay S, Lookstein R, Misra S, Mureebe L, Olin JW, Patel RA, Regensteiner JG, Schanzer A, Shishehbor MH, Stewart KJ, Treat-Jacobson D, Walsh ME. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol, 2017; 69: 1465-1508
3) Conte MS, Pomposelli FB, Clair DG, Geraghty PJ, McKinsey JF, Mills JL, Moneta GL, Murad MH, Powell RJ, Reed AB, Schanzer A, Sidawy AN. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication. J Vasc Surg, 2015; 61: 2S-41S
4) Dormandy JA, Rutherford B. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic Inter-Society Consensus (TASC). J Vasc Surg, 2000; 31: S1-S296
5) Johnston KW. Femoral and popliteal arteries: reanalysis of results of balloon angioplasty. Radiology, 1992; 183: 767-771
6) Minar E, Pokrajac B, Maca T, Ahmadi R, Fellner C, Mittlböck M, Seitz W, Wolfram R, Pötter R. Endovascular brachytherapy for prophylaxis of restenosis after femoropopliteal angioplasty: results of a prospective randomized study. Circulation, 2000; 102: 2694-2699
7) Capek P, McLean GK, Berkowitz HD. Femoropopliteal angioplasty: factors influencing long-term success. Circulation, 1991; 83: Suppl 2: 170-180
8) Schillinger M, Sabeti S, Loewe C, Dick P, Amighi J, Mlekusch W, Schlager O, Cejna M, Lammer J, Minar E. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med, 2006; 354: 1879-1888
9) Sabeti S, Schillinger M, Amighi J, Sherif C, Mlekusch W, Ahmadi R, Minar E. Primary patency of femoropopliteal arteries treated with nitinol versus stainless steel self-expanding stents: propensity score-adjusted analysis. Radiology, 2004; 232: 516-521
10) Laird JR, Katzen BT, Scheinert D, Lammer J, Carpenter J, Buchbinder M, Dave R, Ansel G, Lansky A, Cristea E, Collins TJ, Goldstein J, Jaff MR. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: Twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc Interv, 2010; 3: 267-276
11) Powell RJ, Jaff MR, Schroë H, Benko A, Diaz-Cartelle J, Müller-Hülsbeck S. Stent placement in the superficial femoral and proximal popliteal arteries with the innova self-expanding bare metal stent system. Catheter Cardiovasc Interv, 2017; 89: 1069-1077
12) Tosaka A, Soga Y, Iida O, Ishihara T, Hirano K, Suzuki K, Yokoi H, Nanto S, Nobuyoshi M. Classification and clinical impact of restenosis after femoropopliteal stenting. J Am Coll Cardiol, 2012; 59: 16-23
13) Soga Y, Iida O, Hirano K, Yokoi H, Nanto S, Nobuyoshi M.J. Mid-term clinical outcome and predictors of vessel patency after femoropopliteal stenting with self-expandable nitinol stent. J Vasc Surg, 2010; 52: 608-615
14) Okuno S, Iida O, Shiraki T, Fujita M, Masuda M, Okamoto S, Ishihara T, Nanto K, Kanda T, Takahara M, Uematsu M. Impact of Calcification on Clinical Outcomes After Endovascular Therapy for Superficial Femoral Artery Disease: Assessment Using the Peripheral Artery Calcification Scoring System. J Endovasc Ther, 2016; 23: 731-737
15) Iida O, Soga Y, Hirano K, Suzuki K, Yokoi H, Nobuyoshi M, Muramatsu T, Inoue N, Nanto S, Uematsu M. Long-term outcomes and risk stratification of patency following nitinol stenting in the femoropopliteal segment: retrospective multicenter analysis. J Endovasc Ther, 2011; 18: 753-761
16) Suzuki K, Iida O, Soga Y, Hirano K, Inoue N, Uematsu M, Yokoi H, Muramatsu T, Nanto S, Nobuyoshi M, Meguro T. Long-term results of the S.M.A.R.T. Control(TM) stent for superficial femoral artery lesions, J-SMART registry. Circ J, 2011; 75: 939-944
17) Gray WA, Feiring A, Cioppi M, Hibbard R, Gray B, Khatib Y, Jessup D, Bachinsky W, Rivera E, Tauth J, Patarca R, Massaro J, Stoll HP, Jaff MR; STROLL Study Investigators. S.M.A.R.T. self-expanding nitinol stent for the treatment of atherosclerotic lesions in the superficial femoral artery (STROLL): 1-year outcomes. J Vasc Interv Radiol, 2015; 26: 21-28
18) Iida O, Soga Y, Hirano K, Okamoto S, Dohi T, Uematsu M, Yokoi H, Nobuyoshi M, Muramatsu T, Fujita M, Nanto S, Nagata S. Retrospective multicentre analysis of S.M.A.R.T. vs. Luminexx nitinol stent implantation for superficial femoral artery lesions (REAL SL) Registry. 5 years' experience. Circ J, 2011; 75: 421-427
19) Schulte KL, Kralj I, Gissler HM, Bagnaschino LA, Buschmann I, Pernès JM, Haage P, Goverde P, Beregi JP, Válka M, Boudny J, Geibel T, Velkoborsky M, Zähringer M, Paetzel C, Fanelli F, Müller-Hülsbeck S, Zeller T, Langhoff R. MISAGO 2: one-year outcomes after implantation of the Misago self-expanding nitinol stent in the superficial femoral and popliteal arteries of 744 patients. J Endovasc Ther, 2012; 19: 774-784
20) Ohki T, Angle JF, Yokoi H, Jaff MR, Popma J, Piegari G, Kanaoka Y; OSPREY investigators. One-year outcomes of the U.S. and Japanese regulatory trial of the Misago stent for treatment of superficial femoral artery disease (OSPREY study). J Vasc Surg, 2016; 63: 370-376
21) Laird JR, Katzen BT, Scheinert D, Lammer J, Carpenter J, Buchbinder M, Dave R, Ansel G, Lansky A, Cristea E, Collins TJ, Goldstein J, Jaff MR; RESILIENT Investigators. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: Twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc Interv, 2010; 3: 267-276
22) Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg, 2007; 45: S5-67

23) Abularrage CJ, Conrad MF, Hackney LA, Paruchuri V, Crawford RS, Kwolek CJ, LaMuraglia GM, Cambria RP. Long-term outcomes of diabetic patients undergoing endovascular infrainguinal interventions. J Vasc Surg, 2010; 52: 314-322
24) Iida O, Uematsu M, Soga Y, Hirano K, Suzuki K, Yokoi H, Muramatsu T, Inoue N, Nanto S, Nagata S. Timing of the restenosis following nitinol stenting in the superficial femoral artery and the factors associated with early and late restenoses. Catheter Cardiovasc Interv, 2011; 78: 611-617
25) Hiramori S, Soga Y, Iida O, Suzuki K, Hirano K, Kawasaki D, Shintani Y, Ando K. Relationship between clinical outcomes and vessel size in endovascular therapy for femoropopliteal lesions. J Vasc Surg, 2017; 65: 1690-1697
26) Laird JR, Katzen BT, Scheinert D, Lammer J, Carpenter J, Buchbinder M, Dave R, Ansel G, Lansky A, Cristea E, Collins TJ, Goldstein J, Jaff MR; RESILIENT Investigators. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc Interv, 2010; 3: 267-276
27) Iida O, Yokoi H, Soga Y, Inoue N, Suzuki K, Yokoi Y, Kawasaki D, Zen K, Urasawa K, Shintani Y, Miyamoto A, Hirano K, Miyashita Y, Tsuchiya T, Shinozaki N, Nakamura M, Isshiki T, Hamasaki T, Nanto S; STOP-IC investigators. Cilostazol reduces angiographic restenosis after endovascular therapy for femoropopliteal lesions in the Sufficient Treatment of Peripheral Intervention by Cilostazol study. Circulation, 2013; 127: 2307-2315
28) Zen K, Takahara M, Iida O, Soga Y, Kawasaki D, Nanto S, Yokoi H, Matoba S; ZEPHYR Investigators. Drug-eluting stenting for femoropopliteal lesions, followed by cilostazol treatment, reduces stent restenosis in patients with symptomatic peripheral artery disease. J Vasc Surg, 2017; 65: 720-725
29) Benjo AM, Garcia DC, Jenkins JS, Cardoso RM, Molina TP, El-Hayek GE, Nadkarni GN, Aziz EF, Dinicolantonio JJ, Collins T. Cilostazol increases patency and reduces adverse outcomes in percutaneous femoropopliteal revascularisation: a meta-analysis of randomised controlled trials. Open Heart, 2014; 1: e000154
30) Soga Y, Hamasaki T, Edahiro R, Iida O, Inoue N, Suzuki K, Yokoi Y, Kawasaki D, Zen K, Urasawa K, Aodo K; STOP-IC investigators. Sustained effectiveness of cilostazol after endovascular treatment of femoropopliteal lesions: midterm follow-up from the sufficient treatment of peripheral intervention by cilostazol (STOP-IC) study. J Endovasc Ther, 2018; 25: 306-312