# Nitinol stenting improves primary patency of the superficial femoral artery after percutaneous transluminal angioplasty in hemodialysis patients: A propensity-matched analysis

**Yoshihiro Kawamura, MD,[a] Hideki Ishii, MD,[a,b] Toru Aoyama, MD,[a] Miho Tanaka, MD,[a] Hiroshi Takahashi, BSc,[a] Yoshitaka Kumada, MD,[a] Takanobu Toriyama, MD,[a]** and **Toyoaki Murohara, MD,[b]** *Nagoya, Japan*

***Background:*** **Although percutaneous transluminal angioplasty (PTA) has become a common therapeutic standard for peripheral artery disease (PAD), high restenosis rates in the superficial femoral artery (SFA) remain a major problem. Nitinol stent implantation is reported to reduce restenosis in SFA after PTA in the general population; however, little is known about whether the nitinol stent improves primary patency after PTA in hemodialysis patients who are at higher risk of revascularization failure. The aim of this study was to clarify the effects of nitinol stent implantation for primary patency in SFA after PTA in hemodialysis patients with PAD.**

***Methods:*** **Eighty consecutive hemodialysis patients (167 SFA lesions) who underwent PTA with nitinol stents from January 2006 to January 2008 were compared with 64 hemodialysis patients (128 SFA lesions) who received stainless steel stents in the preceding 2 years. In the follow-up study to 2 years, incidence of restenosis, amputation, and all-cause mortality were analyzed. End points between the groups were examined with the Kaplan-Meier and log-rank methods. Prognostic values for end points were calculated by a Cox univariate analysis and Cox multivariable regression models. To statistically minimize the differences in each stent group, a propensity-matched analysis was also performed using the model including male gender, age, diabetes, hypertension, hyperlipidemia, smoking, incidence of ulcer/gangrene, and TransAtlantic Inter-Society Consensus (TASC) type C+D.**

***Results:*** **The 2-year primary patency rate was 58% in the nitinol group vs 42% in the stainless steel group (hazard ratio [HR], 0.58; 95% confidence interval [CI], 0.39-0.84; $P = .0045$), despite a higher prevalence of TASC C+D lesion in the nitinol group (68% vs 49%, $P = .0014$). In 108 lesions matched after propensity score analysis, the primary patency for 2 years was 64% in the nitinol group vs 42% in the stainless steel group (HR, 0.39; 95% CI, 0.24-0.65; $P = .0003$). Cox multivariate models showed nitinol stent (HR, 0.42; 95% CI, 0.25-0.73; $P = .002$), age (HR, 1.04; 95% CI, 1.01-1.08; $P = .031$), and incidence of ulcer/gangrene (HR, 2.35; 95% CI, 1.17-4.75; $P = .017$) were independent predictors of restenosis.**

***Conclusion:*** **These data suggest that nitinol stent implantation improves primary patency in SFA after PTA compared with the stainless steel stent, even in hemodialysis patients with PAD. (J Vasc Surg 2009;50:1057-62.)**

Percutaneous transluminal angioplasty (PTA) has been an accepted selective treatment method for peripheral artery disease (PAD).[1-3] Endovascular stenting might have beneficial effects on preventing elastic recoil and residual arterial dissection, resulting in an improved patency after PTA. Because of in-stent hyperplasia, however, a relatively higher restenosis rate is a clinical limitation after PTA with stainless steel stents for lesions of the femoropopliteal (FP) arteries.[4-7] On the other hand, the use of nitinol stents has been shown to improve primary patency in FP lesions compared with balloon angioplasty or stainless steel stents, or both.[8-14] Therefore, PTA with nitinol stents has been commonly performed for FP lesions.

Recently, PTA has also become an effective therapy for PAD in patients with end-stage renal disease (ESRD) requiring hemodialysis.[15] PAD is frequently seen in patients on hemodialysis. Thus, PTA is one of the most expected strategies that might improve clinical outcome in hemodialysis patients with PAD. Clinical outcomes after PTA are not always satisfactory in patients on hemodialysis, however, because they have vascular calcification and diffuse lesions. It is unclear in such situations whether nitinol stents reduce restenosis after PTA for the superficial femoral arteries (SFA). The aim of the present study was to evaluate the effects of nitinol stents vs steel stents on preventing restenosis in hemodialysis patients with SFA lesions.

## METHODS

The protocol for this study was approved by the hospital ethics committee.

**Study population.** From January 2006, the Smart nitinol stent (Smart Cordis, Miami, Fla) has been available

From the Cardiovascular Center, Nagoya Kyoritsu Hospital,[a] and Department of Cardiology, Nagoya University Graduate School of Medicine,[b] Nagoya, Japan.

Competition of interest: none.

Reprint requests: Hideki Ishii, Department of Cardiology, Nagoya University Graduate School of Medicine, 65, Tsurumai-cho, Showa-ku, Nagoya 466-8550, Japan (e-mail: hkishii@med.nagoya-u.ac.jp).

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in Nagoya Kyoritsu Hospital. We performed successful elective PTA with the nitinol stent for peripheral artery stenosis causing significant obstruction of SFA in 80 consecutive hemodialysis patients with 167 lesions from January 2006 to January 2008. They were included as the nitinol stent group. In the preceding 2 years, 64 consecutive hemodialysis patients with 128 lesions were treated with the Easy Wallstent stainless steel stents (Boston Scientific, Baltimore, Md) and were included as the stainless steel stent group. PTA was unsuccessful in four patients, who were excluded from the study.

**Protocol.** PTA was performed with standard techniques. All patients received oral aspirin for at least 7 days before PTA. The procedures were performed through the ipsilateral femoral artery with an antegrade approach in patients without lesions near the SFA origin. The approach in patients with such lesions was from the contralateral femoral artery. Intra-arterial injection of heparin (5000 IU) was administered through the sheath after arterial access was achieved. A stent was implanted in case of an insufficient PTA result with balloon alone: a residual stenosis with a luminal diameter >30%, comprising 13 lesions (7.8%) in the nitinol group and 7 (5.5%) in the stainless steel group, or a residual flow-limiting dissection after balloon dilatation, comprising 154 (92.2%) in the nitinol group and 121 (94.5%) in the stainless steel group.

Follow-up examinations including Doppler ultrasound scanning and clinical observations had been conducted 3 months after PTA and every 6 months thereafter up to 2 years at most. In case of suspicion of restenosis after PTA including by abnormal Doppler waveform, duplex ultrasound (DU) arteriography was performed.

The primary end point was incidence of restenosis, defined as angiographic luminal diameter narrowing >50% in diameter anywhere within the stent or within the 5 mm borders proximal or distal to the stent, or peak systolic velocity ratio of ≥2.4 by DU scans.[16] The secondary end points included amputation due to lower extremity ischemia and all-cause mortality. These end points were obtained from hospital records and telephone interviews with patients by two independent reviewers who were blinded to PTA procedures. Lesions and critical limb ischemia were characterized according to TransAtlantic Inter-Society Consensus (TASC) classification as published.[17] In the present study, we divided lesions into the TASC criteria A+B or C+D for the analysis. Amputation was defined as all amputations, including toe or foot amputation. Diabetes was diagnosed in patients who had a previous or current diagnosis of diabetes or who had abnormal results from the oral glucose tolerance test or hemoglobin $A_{1c}$ levels ≥6.5%.

**Statistical analysis.** All statistical analyses were performed using SAS 6.10 software (SAS Institute, Cary, NC). Continuous variables are presented as mean ± standard deviation and were compared using the *t* test. The end points between the nitinol stent and stainless steel stent groups were examined with the Kaplan-Meier method and compared using the log-rank test. Prognostic values for end points were calculated by a Cox univariate analysis; furthermore, Cox multivariable regression models were used to determine predictors for the end points. Factors as indicated by $P < .1$ on the univariate Cox analysis were entered into the multivariable Cox regression models. To statistically minimize the differences in each stent group to more fully assess the effect of the stent type, we performed a propensity-matched analysis. Based on a multivariable logistic regression model, each patient was assigned a propensity score. Covariates in the model included gender, age, diabetes, hypertension, hyperlipidemia, smoking, ulcer/gangrene, TASC C+D, and length of stent. The area under the receiving operating characteristics curve associated between nitinol stent use and the obtained propensity score was 0.80. Patients in the nitinol group and those in the control group were matched 1:1 with two-digit on the basis of the estimated propensity score. Freedom from restenosis and clinical events were then analyzed in the propensity-matched groups. Values of $P < .05$ were considered statistically significant.

## RESULTS

Antegrade access was used in 77 patients (96.3%) in the nitinol group and in 61 (95.3%) in the stainless steel group. Contralateral access was used in three patients (3.7%) in the nitinol group and in three (4.7%) in the stainless steel group. For all lesions, a final luminal diameter stenosis of <30% without angiographically visual arterial dissection was seen. No in-hospital complications occurred, including death, or necessity for additional surgical procedures. No patients were lost to follow-up. Mean follow-up was 13 ± 6 months in the nitinol stent group and 18 ± 7 months in the stainless steel group.

Table I summarizes the baseline clinical characteristics. There were significant differences in age, incidence of diabetes, and TASC classification. The average age was older in the stainless steel group, and the nitinol stent group had higher incidences of diabetes and TASC type C+D.

All patients underwent DU imaging, which detected restenosis in 33 patients (41.3%) in the nitinol group and in 38 patients (59.4%) in the stainless steel group. Of those, 31 patients (38.8%) in the nitinol group and 36 patients (56.3%) in the stainless steel group underwent angiography and were found to have restenosis. Fig 1 shows Kaplan-Meier curves for the primary end point of freedom from restenosis. The event-free rate from restenosis for 2 years was 64% in the nitinol group vs 42% in the stainless steel group (hazard ratio [HR], 0.58; 95% confidence interval [CI], 0.39-0.84; $P = .0045$) despite the higher prevalence of TASC C+D lesions in nitinol group (68% vs 49%, $P = .0014$). Multivariable analysis to determine effects of the nitinol stent, even after adjusting for other risk factors at baseline, showed the beneficial effect of the nitinol stent remained significant and independent (HR, 0.59; 95% CI, 0.40-0.88; $P = .011$; Table II). However, the nitinol group required four amputations (5.0%), comprising above knee in 1, below knee in 1, and toes in 2, and 11 amputations (17.2%) occurred in the stainless steel group, comprising above knee in 2, below knee in 3, foot in 1, and toes in 5

**Table I.** Characteristics of patients

| *Characteristics* *No. (%) or mean ± SD* | *Stent type* *Nitinol* | *Stainless steel* | P |
|---|---|---|---|
| Patients, no. | 80 | 64 | |
| Male | 44 (55) | 43 (67) | .14 |
| Age, yr | 65 ± 11 | 69 ± 9 | .017 |
| Diabetes | 65 (81) | 40 (63) | .012 |
| Hypertension | 63 (79) | 45 (70) | .25 |
| Hyperlipidemia | 22 (28) | 11 (17) | .14 |
| Smoking | 13 (16) | 19 (30) | .053 |
| Coronary artery disease | 46 (58) | 38 (59) | .82 |
| Stroke | 6 (8) | 10 (16) | .13 |
| Indication for PTA | | | .32 |
| Severe claudication | 36 (45) | 36 (56) | |
| Rest pain | 16 (20) | 8 (13) | |
| Ulcer/gangrene | 28 (35) | 20 (31) | |
| Pre-op ABI | 0.63 ± 0.30 | 0.67 ± 0.25 | .27 |
| TASC classification (%) | | | .0014 |
| Lesions, no. | 167 | 128 | |
| Type A+B | 54 (32) | 65 (51) | |
| Type C+D | 113 (68) | 63 (49) | |
| Stent length, mm | 61.4 ± 26.4 | 55.4 ± 18.8 | .014 |
| Medication | | | |
| Statins | 14 (18) | 8 (13) | .43 |
| Warfarin | 6 (8) | 9 (14) | .20 |
| Ticlopidine | 44 (55) | 32 (50) | .55 |
| Cilostazol | 23 (29) | 25 (39) | .19 |
| Sarpogrelate | 19 (24) | 13 (20) | .62 |

*ABI,* Ankle-brachial index; *PTA,* percutaneous transluminal angioplasty; *SD,* standard deviation; *TASC,* TransAtlantic Inter-Society Consensus.

(HR 0.42; 95% CI 0.12-1.49; $P = .17$). Six patients (7.5%) in the nitinol group and 15 (23.4%) in the stainless steel group died during the follow-up period (HR, 0.53; 95% CI, 0.21-1.12; $P = .076$).

**Propensity-matched analysis.** In 108 lesions matched after propensity score analysis, baseline characteristics were well matched (Table III). Variables including age, incidence of diabetes, smoking status, and TASC classification were also similar between the two groups.

The event-free rate from restenosis for 2 years was 64% in the nitinol group compared with 42% in the stainless steel group (42%), which was significant (HR, 0.39; 95% CI, 0.24-0.65; $P = .0003$; Fig 2). On Cox multivariate models, nitinol stent (HR, 0.42; 95% CI, 0.25-0.73; $P = .002$), age (HR, 1.04; 95% CI, 1.01-1.08; $P = .031$), and incidence of ulcer/gangrene (HR, 2.35; 95% CI, 1.17-4.75; $P = .017$) were independent predictors of restenosis (Table IV). The event-free rate from target lesion revascularization (TLR) within the first 2 years after stenting was significantly higher in the nitinol group than in the stainless steel group (69% vs 49%; HR, 0.40; 95% CI, 0.18-0.89; $P = .024$; Table V). However, the event-free rate from amputation for 2 years was 94% in the nitinol group and 83% in the stainless steel group, which was not statistically significant (HR, 0.36; 95%, CI 0.08-1.64; $P = .18$). Treatment with the nitinol stent was of borderline significance for survival from all-cause death (88% in the nitinol group and 71% in the stainless steel group; HR, 0.35; 95% CI, 0.10-1.20; $P = .093$).

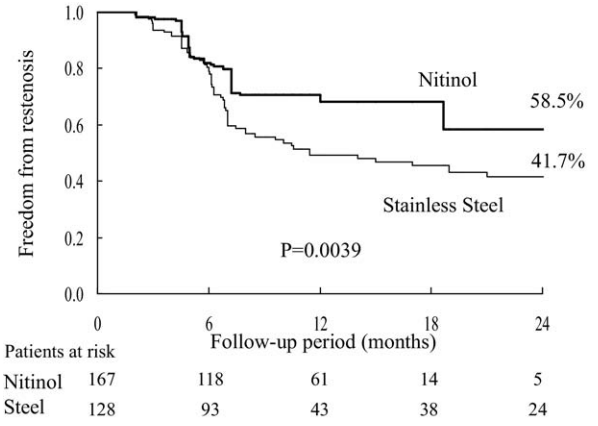


**Fig 1.** Kaplan-Meier curves show cumulative primary patency after stent implantation.

## DISCUSSION

To our knowledge, this is the first report that implantation of nitinol stents for SFA in patients receiving long-term hemodialysis is associated with significantly improved primary patency rates compared with stainless steel stents. Patients who require hemodialysis are at high risk of accelerated atherosclerosis.[18,19] PAD is a common disease in patients receiving maintenance hemodialysis, and its prevalence in the population is increasing, up to 15% in the United States.[20]

Because of the increased rate of amputation and death after surgical revascularization in patients with renal insufficiency, especially at high rates for dialysis patients,[21] the less-invasive PTA procedure might be considered the first-choice therapeutic option for hemodialysis patients. However, one reason why PTA is not necessarily thought to be the best strategy of treatment for PAD in hemodialysis patients is that these patients frequently have complex lesions.[22,23] Our finding was clinically of great significance because the effects of treatments are not well studied in hemodialysis patients in whom neointimal growth is pronounced.[24,25]

In general, treatments for FP lesions are controversial. Studies have shown that stainless steel stents in FP lesions do not improve primary patency.[4-7] Until now, several strategies, among them drug-eluting stents and vascular brachytherapy, have been attempted in FP lesions.[8-14,26-28] Reports on these strategies have suggested that nitinol stent implantation improves primary patency rates in FP/SFA lesions.[8-14]

Schillinger et al[14] have suggested that implantation of nitinol stents in the SFA significantly prevents restenosis on DU imaging compared with a balloon angioplasty group (37% vs 63%, $P = .01$).[14] Sabeti et al[11] reported that cumulative primary patency rates at 6, 12, and 24 months were 85%, 75%, and 69% after nitinol stenting, respectively, vs 78%, 54%, and 34% after stainless steel stenting ($P = .008$, log-rank test in propensity score-adjusted analysis).

**Table II.** Predictors for restenosis

| | *Univariate* | | *Multivariate* | |
|---|---|---|---|---|
| *Predictor* | *HR (95% CI)* | P | *HR (95% CI)* | P |
| Nitinol stent | 0.58 (0.39-0.84) | .0045 | 0.59 (0.40-0.88) | .011 |
| Male | 1.01 (0.99-1.03) | .25 | | |
| Age | 1.06 (1.04-1.07) | .0032 | 1.04 (1.01-1.07) | .019 |
| Diabetes | 2.09 (1.25-3.48) | .0046 | 2.86 (1.15-5.64) | .023 |
| Hypertension | 1.24 (0.82-1.90) | .30 | | |
| Hyperlipidemia | 1.31 (0.86-1.19) | .22 | | |
| Smoking | 1.32 (0.84-2.06) | .23 | | |
| CAD | 1.28 (0.85-1.93) | .24 | | |
| Stroke | 1.87 (0.82-4.28) | .14 | | |
| Pre-op ABI | 0.63 (0.26-1.52) | .31 | | |
| Ulcer/gangrene | 2.49 (1.51-4.11) | .0004 | 2.20 (1.37-3.51) | .0010 |
| Statins | 0.58 (0.30-1.19) | .19 | | |
| Warfarin | 0.71 (0.22-2.29) | .57 | | |
| Ticlopidine | 0.74 (0.43-1.28) | .29 | | |
| Cilostazol | 0.54 (0.26-1.15) | .11 | | |
| Sarpogrelate | 0.93 (0.53-1.63) | .80 | | |
| TASC C+D lesions | 1.75 (1.21-2.54) | .0032 | 1.62 (0.89-2.96) | .11 |
| Stent length | 1.01 (0.99-1.02) | .28 | | |

*ABI,* Ankle-brachial index; *CAD,* coronary artery disease; *CI,* confidence interval; *HR,* hazard ratio; *TASC,* TransAtlantic Inter-Society Consensus.

**Table III.** Characteristics of patients after propensity adjusting

| *Characteristic No. (%) or mean ± SD* | *Nitinol* | *Stainless steel* | P |
|---|---|---|---|
| Patients, no. | 59 | 58 | |
| Male | 35 (59) | 40 (69) | .28 |
| Age, yr | 65 ± 11 | 67 ± 8 | .12 |
| Diabetes | 46 (78) | 40 (69) | .27 |
| Hypertension | 43 (73) | 40 (69) | .64 |
| Hyperlipidemia | 15 (25) | 12 (21) | .54 |
| Smoking | 13 (22) | 16 (28) | .49 |
| CAD | 37 (63) | 34 (59) | .65 |
| Stroke | 4 (7) | 7 (12) | .33 |
| Indication for PTA | | | .37 |
| Severe claudication | 28 (48) | 34 (59) | |
| Rest pain | 12 (20) | 7 (12) | |
| Ulcer/gangrene | 19 (32) | 17 (29) | |
| Pre-op ABI | 0.63 ± 0.29 | 0.67 ± 0.18 | .56 |
| Statins | 11 (19) | 9 (16) | .65 |
| Warfarin | 4 (7) | 7 (12) | .33 |
| Medication | | | |
| Ticlopidine | 33 (56) | 30 (52) | .65 |
| Cilostazol | 17 (29) | 23 (40) | .22 |
| Sarpogrelate | 12 (20) | 12 (21) | .96 |
| TASC classification | | | .26 |
| Lesions, no. | 108 | 108 | |
| Type A+B | 38 (35) | 46 (43) | |
| Type C+D | 70 (65) | 62 (57) | |
| Stent length, mm | 60.3 ± 22.1 | 56.6 ± 16.8 | .19 |

*ABI,* Ankle-brachial index; *CAD,* coronary artery disease; *PTA,* percutaneous transluminal angioplasty; *SD,* standard deviation; *TASC,* TransAtlantic Inter-Society Consensus.

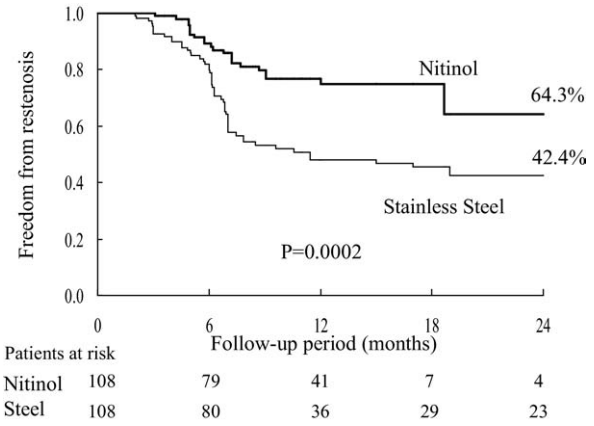


**Fig 2.** Kaplan-Meier curves show cumulative primary patency after stent implantation in propensity-adjusted groups.

Nitinol has a unique mechanical property of reduced thrombogenicity of its surface that results in reducing in-stent neointimal proliferation.[29] The major cause of restenosis after PTA is thought to be neointimal hyperplasia.[30] Plasma coagulation factors are also activated in hemodialysis patients.[31] These actions might be related to mural thrombus formation, leading to an early stage of restenosis after PTA. A nitinol stent, therefore, is one of the most logical devices for PTA.

Although we found efficacies of nitinol stent implantation for SFA lesions in hemodialysis patients compared with stainless steel stents, the primary patency for 2 years was 65% in the nitinol group. Lugmayr et al[32] reported that the primary 2-year patency rate was 85% after treatment of complex lesions in the SFA and popliteal artery in nondialysis patients. Thus, the restenosis rate was quite higher in hemodialysis patients, showing the difficulty of treatment for PAD in hemodialysis patients. In such situations, much intensive care, including medical treatment after PTA, might be effective. A recent report has suggested that cilostazol treatment not only prevents restenosis but also

**Table IV.** Predictors for restenosis after propensity adjustment

| | *Univariate* | | *Multivariate* | |
|---|---|---|---|---|
| *Predictor* | *HR (95% CI)* | P | *HR (95% CI)* | P |
| Nitinol stent | 0.39 (0.24-0.65) | .0003 | 0.42 (0.25-0.73) | .0020 |
| Male | 1.06 (0.65-1.73) | .80 | . . . | . . . |
| Age | 1.04 (1.02-1.07) | .0002 | 1.04 (1.01-1.08) | .031 |
| Diabetes | 2.11 (1.08-4.13) | .027 | 2.43 (0.90-5.57) | .078 |
| Hypertension | 1.17 (0.44-3.12) | .74 | . . . | . . . |
| Hyperlipidemia | 1.13 (0.68-1.86) | .63 | . . . | . . . |
| Smoking | 1.38 (0.83-2.32) | .22 | . . . | . . . |
| Coronary artery disease | 1.06 (0.63-1.81) | .81 | . . . | . . . |
| Stroke | 1.08 (0.47-2.53) | .85 | . . . | . . . |
| Pre-op ABI | 0.49 (0.18-1.35) | .17 | . . . | . . . |
| Ulcer/gangrene | 2.20 (1.39-3.48) | .0008 | 2.35 (1.17-4.75) | .017 |
| Statins | 0.72 (0.43-1.21) | .22 | . . . | . . . |
| Warfarin | 0.87 (0.32-2.39) | .78 | . . . | . . . |
| Ticlopidine | 0.66 (0.41-1.09) | .15 | . . . | . . . |
| Cilostazol | 0.57 (0.28-1.15) | .12 | . . . | . . . |
| Sarpogrelate | 0.93 (0.53-1.62) | .80 | . . . | . . . |
| TASC C+D lesions | 2.01 (0.97-4.13) | .058 | 1.38 (0.62-3.11) | .42 |
| Stent length | 1.01 (0.99-1.02) | .13 | . . . | . . . |

*ABI,* Ankle-brachial index; *CI,* confidence interval; *HR,* hazard ratio; *TASC,* TransAtlantic Inter-Society Consensus.

**Table V.** Event-free survival at 2 years after propensity score matching

| *Event* | *Nitinol* | *Stainless steel* | *HR (95% CI)* | P |
|---|---|---|---|---|
| TLR, % | 69 | 49 | 0.40 (0.18-0.89) | .024 |
| Amputation, % | 94 | 83 | 0.36 (0.08-1.64) | .18 |
| All-cause death, % | 88 | 71 | 0.35 (0.10-1.20) | .093 |

*CI,* Confidence interval; *HR,* hazard ratio; *TLR,* target lesion revascularization.

improves clinical outcomes after PTA in hemodialysis patients with PAD.[33] Additional pharmacologic strategies like this might have beneficial effects on clinical outcome.

We could not demonstrate a statistically significant difference in rates of amputation and death in the study, although there were tendencies toward higher reduction rates of those adverse outcomes in patients treated with nitinol stents. This might be due to a relatively small sample size, and further investigations are needed to clarify the results.

The present study has some limitations. First, it was retrospective, and the assignment to nitinol or stainless steel stents was not randomized. Although we used propensity score-adjusted analysis, much chance for bias existed. There might be a time-related lag bias and treatment selection bias. In other words, no nitinol stents were used in the first 2 years, and no steel stents were used in the second 2 years. Second, this was a single-center study with a small sample size, as described. Third, we used the Smart stent as the only nitinol stent in the present study and have no data on other nitinol stents. Fourth, we could not perform follow-up angiography in all patients, so some patients might have had a normal Doppler waveform or no ischemic symptoms because of adequate collateral flow even if restenosis at the stent site existed.

## CONCLUSIONS

Nitinol stent implantation for SFA lesions is a useful strategy in hemodialysis patients who are at high risk of atherosclerosis and results in improving primary patency and reducing a TLR rate. A large-scale randomized multicenter study is needed to confirm the results of this study.

## AUTHOR CONTRIBUTIONS

Conception and design: YK, HI
Analysis and interpretation: TA, HT
Data collection: MT, YK, TT
Writing the article: YK, HI, YK
Critical revision of the article: YK, HT, TA, TM
Final approval of the article: TM
Statistical analysis: HT
Obtained funding: Not applicable
Overall responsibility: TM

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