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Influence of Infrapopliteal Runoff Vessels on Primary Patency after Superficial Femoral Artery Angioplasty with Stenting in Patients with Claudication

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Purpose: The number of infrapopliteal runoff vessels seems to be one of the factors influencing arterial patency in patients who had undergone superficial femoral artery (SFA) angioplasty with stenting. However, the effectiveness of infrapopliteal runoff vessels in predicting patency during SFA angioplasty remains unclear. This study aimed to determine whether the number and quality of infrapopliteal runoff vessels affect the primary patency after SFA angioplasty with stenting in patients with claudication.

Materials and Methods: This study reviewed a retrospective database of patients with claudication who underwent SFA angioplasty with stenting between March 2011 and December 2016. The preoperative computed tomography findings of all patients were reviewed to assess infrapopliteal runoff vessels. The Trans-Atlantic Inter-Society (TASC) II classification and modified Society for Vascular Surgery (SVS) runoff score were used for subsequent analysis. Kaplan–Meier survival curves were constructed, and Fisher's exact and chi-square tests were used for data analysis.

Results: A total of 153 limbs of 122 patients (88.2% male, mean age: 69.1 years) underwent SFA angioplasty with stenting. The overall primary patency rates of TASC II A/B and C/D cases were 77.1% and 31.2%, respectively, at 36 months ($P<0.001$). The primary patency rates at 36 months using the modified SVS runoff scoring system were 64.6% and 49.8% for the good-to-compromised (≤9 points) and poor (≥10 points) runoff groups, respectively ($P=0.011$).

Conclusion: The modified SVS runoff scoring system is effective in predicting primary patency after SFA angioplasty with stenting in patients treated for claudication.

Key Words: Vascular patency, Femoral artery, Stents, Angioplasty

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INTRODUCTION

Angioplasty and stenting of the superficial femoral artery (SFA) have been accepted as the first-line treatments for peripheral artery disease [1-3]. The duration of maintaining patency without requiring a repeated intervention has been a concern in endovascular treatments [4]. Identifying the factors that influence the efficacy of SFA angioplasty with nitinol stent placement is important for predicting primary patency. Previous studies have shown that hypercholesterolemia, cerebrovascular disease, presence of a popliteal stent, and current or previous smoking history are predictors of restenosis or occlusion [5]. Moreover, dialysis dependency, warfarin use, and one or fewer runoff vessel have been shown to be associated with a worsened primary patency after angioplasty and stenting [6]. However, the clinically important predictors are still unclear. Runoff, as defined by the Society for Vascular Surgery (SVS) guidelines, has been widely used with different scoring methods to evaluate patency. In particular, the modified SVS runoff scoring system has been used to analyze the long-term outcomes of SFA lesions [7-9]. Several studies have reported the effectiveness of measuring the number of infrapopliteal runoff vessels, such as the anterior tibial, posterior tibial, and peroneal arteries [10-12]. In contrast, some authors reported that runoff does not seem to influence the overall stent patency outcomes [8,13]. The influence of the infrapopliteal runoff vessels on the outcomes of SFA angioplasty with stenting remains unclear. This study aimed to analyze the influence of infrapopliteal runoff vessels on the long-term outcomes of SFA angioplasty with stenting, using the modified SVS scoring system.

MATERIALS AND METHODS

A total of 153 limbs of 122 patients with claudication underwent primary SFA angioplasty with stenting between March 2011 and December 2016 (70-month period), according to the SVS guidelines. After obtaining approval from the institutional review board of Biomedical Research Institute, Pusan National University Hospital (approval No. E-1911-009-085), the patients' data were retrospectively reviewed. The requirement for obtaining informed consent from patients was waived owing to the retrospective nature of the study. Patients with acute limb ischemia, chronic limb-threatening ischemia, pedal intervention, neoplastic disease, and clotting disorder were excluded. Preoperative computed tomography angiography (CTA) images were reviewed in all cases to assess the infrapopliteal runoff vessels, which were scored according to the modified SVS criteria [14-17]. A vessel was considered patent if it had <50% stenosis and was continuous down to the ankle level. CTA images with bone setting (width, 2,056 Hounsfield units; level, 150 Hounsfield units) were checked to differentiate the vessel lumen and calcification in the Picture Archiving and Communication System. Intraoperative angiography images were rechecked for calculating the runoff score of the infrapopliteal runoff vessels during the procedure.

1) Two different scoring systems

Two different scoring systems were used for subsequent analysis. The first scoring system was based on the SVS guidelines. After the patent tibial vessels were examined using preoperative CTA with intraoperative angiography, the number of infrapopliteal runoff vessels was counted and scored as 0, 1, 2, and 3. The patients were divided into the good (two or three vessels) and poor (zero or one vessel) groups.

In the second scoring system, the quality of runoff vessels was checked according to the modified SVS guidelines and scored on the basis of the degree of disease severity. Infrapopliteal artery scores were multiplied as follows: 0%-20% stenosis, ×1; 21%-49% stenosis, ×2; 50%-99% stenosis, ×2.5; <50% occlusion of vessel length, ×3; and >50% occlusion of vessel length, ×3 with 1 point added [14-17]. A higher score, with a maximum of 19 points, indicated a severer disease. The patients were divided into the following two groups: good-to-compromised (≤9 points) and poor (≥10 points) runoff groups. The primary patency rates based on runoff (good vs. poor) within the Trans-Atlantic Inter-Society (TASC) II classification, determined using the number of tibial runoff vessels and using the modified SVS score, were also calculated to compare the two scoring systems. Thereafter, the primary patency obtained using each scoring system was schematized during the follow-up period.

2) Follow-up

The recorded postintervention complications included infection, hemorrhage, ischemic heart disease, and death. The arterial brachial index (ABI) was measured in all patients by a single vascular surgeon. All other measurements were performed by a single vascular surgeon. Follow-up examination was conducted at 6-month intervals, alternating between ABI and CTA assessments. Thereafter, the annual ABI was evaluated. Patients with an ABI decrease of >0.15, ≥50% stenosis, and remaining symptoms from the preoperative to the follow-up period, as well as those suspected of having restenosis after endovascular treatment, underwent additional intervention. Following the SVS guidelines, loss of patency was defined as ≥50% stenosis or stent occlusion at the operative site [14]. The sensitivity and specificity values for the detection of >50% stenosis were both >90% in several CTA studies [18,19]. To analyze the survival curve, the duration of primary patency was also recorded. The collected patient data were sex, diabetes mellitus (fasting serum glucose >110 mg/dL or hemoglobin A1c >7%), chronic kidney disease (serum creatinine ≥1.5 mg/dL or dialysis dependence), hypertension (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg), hyperlipidemia (fasting serum cholesterol >200 mg/dL, triglyceride >200 mg/dL, or low-density lipoprotein >130 mg/dL), smoking, cardiovascular disease, and chronic obstructive pulmonary diseases.

3) Procedures

All procedures were performed at the hybrid suite in the operating room with appropriate anesthesia based on the patients' risk status and the potential intraoperative hemodynamic changes. The common femoral artery was punctured under ultrasound guidance to achieve the safest approach to obtaining vascular access. All procedures were confirmed with fluoroscopy, and an intraluminal approach was employed. Ipsilateral or contralateral approaches were used for the target lesion. A 6-Fr introducer sheath was mainly used, and 0.018- and 0.035-inch guidewires were used to cross the lesions. The following self-expanding bare nitinol stents were deployed in all cases: EverFlex (Medtronic/Covidien, Plymouth, MN, USA), SMART stent (Cordis, Miami, FL, USA), and LifeStent (Bard Peripheral Vascular, Tempe, AZ, USA). Postdilatation was routinely performed. Stent selection depended on the surgeon's preference. All patients were administered an intra-arterial bolus of heparin (2,000-5,000 IU, <60 IU/kg) during the procedure. After the intervention, a combination of aspirin (100 mg/day) and clopidogrel (75 mg/day) was administered for at least 3 months. The patients received life-long aspirin therapy thereafter.

4) Statistical analysis

Univariate analysis was performed for risk factors affecting primary patency. Kaplan–Meier methods were used for survival analysis on an intention-to-treat basis. Differences were analyzed using the log-rank test. Two-tailed Fisher's exact test was used to compare categorical variables. P<0.05 was considered significant. All tests were performed using IBM SPSS software (version 21; IBM Co., Armonk, NY, USA).

RESULTS

1) Characteristics of the study patients

A total of 204 patients underwent isolated SFA angioplasty with stenting during the study period. Of these, 66 patients who were lost to follow-up, 7 patients with acute limb ischemia, and 9 patients who died of pneumonia and/or cancer were excluded. The data of the remaining 153 limbs in 122 patients, including 135 limbs of male patients (88.2%) and 18 limbs of female patients (11.8%) were analyzed. The patients' mean age was 69.1 years (range, 44-84 years). None of the risk factors showed a significant influence on primary patency in the univariate analysis. However, the poor runoff group (≥10 points) had a relatively higher hazard ratio (HR) in the analysis according to the modified SVS guidelines (P=0.013; Table 1). The mean follow-up period was 27.8 months (range, 0-76 months; median, 24 months). A total of 91 patients underwent isolated SFA stenting, whereas 31 patients underwent SFA stenting of both limbs.

Table 1. Risk factors analyzed using a univariate Cox proportional hazard model

Risk factor	Limb (n=153)	HR (95% CI)	P-value
Diabetes mellitus	79 (51.6)	0.933 (0.539-1.614)	0.933
Hypertension	109 (71.2)	0.715 (0.405-1.261)	0.246
Hyperlipidemia	3 (2.0)	NA	NA
Smoking history	91 (59.5)	1.045 (0.599-1.824)	0.876
CVA	19 (12.4)	0.585 (0.211-1.626)	0.304
CAD	22 (14.4)	0.738 (0.314-1.737)	0.486
CKD	25 (16.3)	0.700 (0.296-1.659)	0.418
COPD	3 (2.0)	0.684 (0.161-2.911)	0.607
Run off 0-5	54 (35.3)	0.767 (0.425-1.386)	0.380
Run off 6-9	68 (44.4)	0.703 (0.395-1.250)	0.230
Run off 10-19	31 (20.3)	2.071 (1.164-3.685)	0.013

Values are presented as number (%).
HR, hazard ratio; CI, confidence interval; CVA, cerebrovascular accident; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; NA, not available.

Table 2. Infrapopliteal runoff vessels

Infrapopliteal runoff vessel	Limb (n=153)
Zero runoff vessel	17 (11.1)
One runoff vessel	
Anterior tibial only	6 (3.9)
Posterior tibial only	15 (9.8)
Peroneal only	15 (9.8)
Two runoff vessels	
Peroneal+anterior tibial	16 (10.5)
Peroneal+posterior tibial	27 (17.6)
Anterior tibial+posterior tibial	15 (9.8)
Three runoff vessels	
Anterior tibial+posterior tibial+peroneal	42 (27.5)

Values are presented as number (%).

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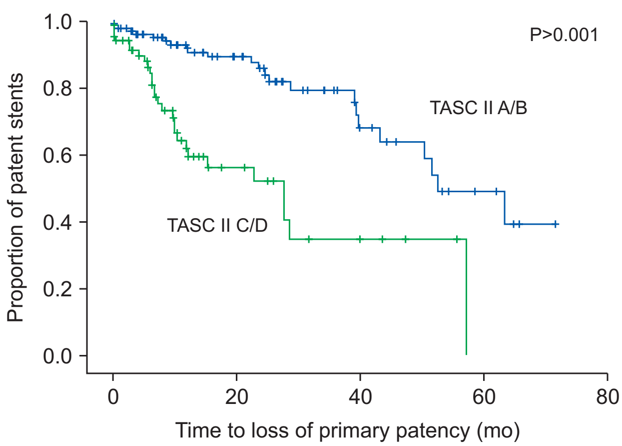
Table 3. Comparison of primary patency based on runoff (good vs. poor) within TASC II classification

TASC II classification	Total	Infrapopliteal runoff vessels		P-value	Modified SVS score		P-value
		Two or three vessels	Zero or one vessel		0-9	10-19	
A	25 (16.3)	20 (20.0)	5 (9.4)	0.093	23 (18.9)	2 (6.5)	0.166
B	71 (46.4)	44 (44.0)	27 (50.9)	0.413	59 (48.3)	12 (38.7)	0.597
C	37 (24.2)	21 (21.0)	16 (30.2)	0.207	30 (24.6)	7 (22.6)	0.367
D	20 (13.1)	15 (15.0)	5 (9.4)	0.331	10 (8.2)	10 (32.3)	0.002
Total	153 (100.0)	100 (100.0)	53 (100.0)	-	122 (100.0)	31 (100.0)	-

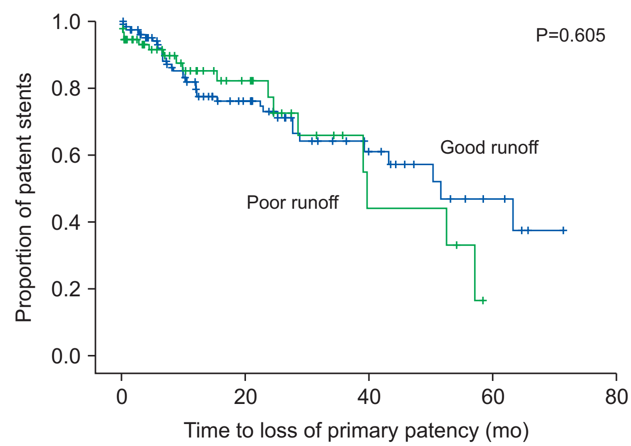
Values are presented as number (%).
TASC, Trans-Atlantic Inter-Society Consensus; SVS, Society for Vascular Surgery; –, not available.



Number at risk (mo)	6	12	24	36	48
TASC II A/B	85 (94.7)	72 (90.0)	45 (83.8)	23 (77.1)	13 (61.6)
TASC II C/D	39 (80.8)	22 (56.1)	13 (46.8)	5 (31.2)	2 (31.2)

Values are presented as number (%).

Fig. 1. Primary patency of patients with Trans-Atlantic Inter-Society Consensus (TASC) II classification A/B lesions versus C/D lesions.



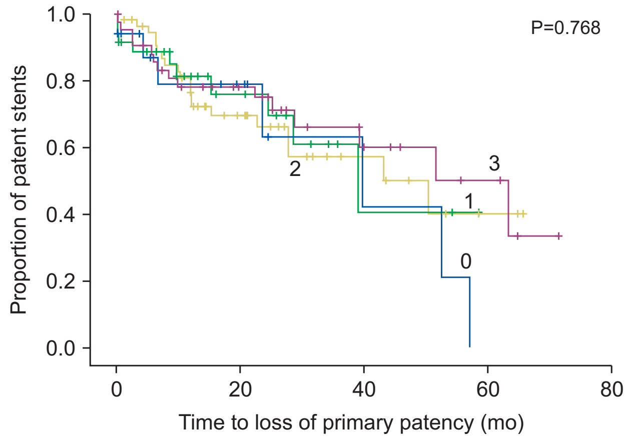
Number at risk (mo)	6	12	24	36	48
Poor runoff	40 (88.3)	29 (81.0)	16 (73.2)	6 (62.4)	4 (41.6)
Good runoff	84 (90.5)	65 (77.3)	42 (70.4)	22 (61.3)	11 (54.5)

Values are presented as number (%).

Fig. 2. Primary patency of patients with good (two or three vessels) and poor (zero or one vessel) runoff vessels.

2) Number of infrapopliteal vessels

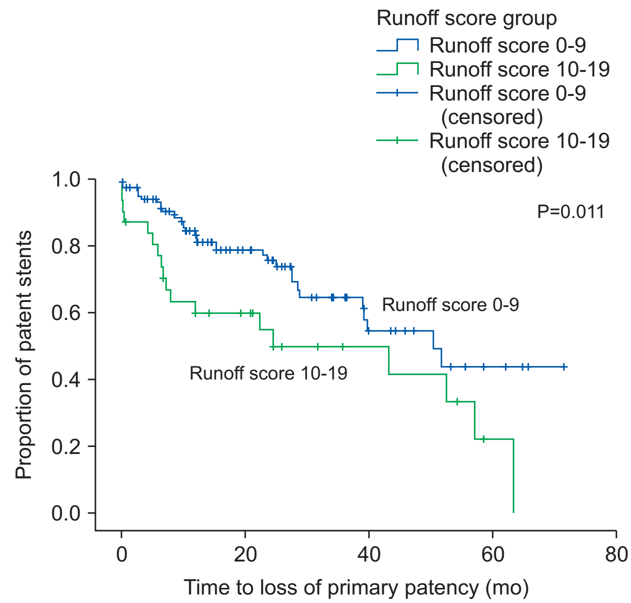
The distribution of the number of runoff vessels detected was specified (Table 2). Seventeen limbs (11.1%) had no runoff vessels detected, 35 limbs (22.8%) had one vessel, 59 limbs (38.6%) had two vessels, and 42 limbs (27.5%) had three vessels. The poor runoff (zero or one vessel) and good runoff (two or three vessels) groups comprised 53 (34.6%) and 100 (65.4%) limbs, respectively. Twenty-five limbs (16.3%) were classified as TASC II A, 71 limbs (46.4%) as TASC II B, 37 limbs (24.2%) as TASC II C, and 20 limbs (13.1%) as TASC II D (Table 3). The Kaplan–Meier curve showed that the primary patency rate of TASC II A or B limbs was 94.7% at 6 months, 90% at 12 months, 83.8% at 24 months, 77.1% at 36 months, and 61.6% at 48 months, whereas that of the TASC II C or D limbs was 80.8% at 6 months, 56.1% at 12 months, 46.8% at 24 months, and 31.2% at 36 and 48 months (Fig. 1). TASC II A or B limbs showed better patency rates than TASC II C or D limbs (P>0.001). Primary patency based on the number of runoff vessels and that based on the modified SVS score were compared. The distribution of the number of runoff vessels in the limbs is shown in Table 3. First, we compared the primary patency between the good (two or three vessels) and poor (zero or one vessel) runoff groups. The primary patency of the good runoff group was 90.5% at 6 months, 77.3% at 12 months, 70.4% at 24 months, 61.3% at 36 months, and 54.5% at 48 months, whereas that of the poor runoff group was 88.3% at 6 months, 81.0% at 12 months, 73.2% at 24 months, 62.4% at 36 months, and 41.6% at 48 months. No significant difference was observed between the two groups (P=0.605; Fig. 2). We analyzed the primary patency according to the number of runoff vessels. The primary patency of the zero runoff vessel group was 86.9% at 6 months, 79.0% at 12 months, 63.2% at 24



Number at risk (mo)	6	12	24	36	48
Zero runoff vessel	11 (86.9)	10 (79.0)	4 (63.2)	3 (63.2)	2 (42.1)
One runoff vessel	29 (88.7)	19 (81.3)	12 (75.9)	3 (60.9)	2 (40.6)
Two runoff vessels	49 (94.4)	35 (76.6)	18 (66.1)	10 (57.2)	5 (50.1)
Three runoff vessels	35 (85.6)	30 (78.1)	24 (75.1)	12 (66.1)	6 (60.1)

Values are presented as number (%).

Fig. 3. Primary patency of patients grouped according to the number of infrapopliteal runoff vessels.



Number at risk (mo)	6	12	24	36	48
Runoff score 0-9	101 (93.0)	78 (83.3)	47 (75.6)	22 (64.6)	10 (54.5)
Runoff score 10-19	23 (77.0)	16 (59.8)	11 (54.8)	6 (49.8)	5 (41.5)

Values are presented as number (%).

Fig. 4. Primary patency of the of good-to-compromised (0-9 points) and poor (10-19 points) groups classified according to the modified Society for Vascular Surgery runoff score.

months, 63.2% at 36 months, and 42.1% at 48 months; that of the one runoff vessel group was 88.7%, 81.3%, 75.9%, 60.9%, and 40.6%, respectively; that of the two runoff vessel group was 94.4%, 76.6%, 66.1%, 57.2%, and 50.1%, respectively; and that of the three runoff vessel group was 85.6%, 78.1%, 75.1%, 66.1%, and 60.1%, respectively. No difference in the primary patency rate was found among the four groups (P=0.768; Fig. 3). The TASC II classification correlated with the primary patency after SFA stenting. Not surprisingly, the number of infrapopliteal vessels decreased with worsening of the TASC II classification (P<0.05), within individual TASC II A, B, and C (P=0.166) and TASC II D (P=0.002) subclasses. Our results showed that although the number of patent infrapopliteal vessels decreased as the TASC II classification worsened, this did not correlate with the patency rates.

3) Modified SVS score

The primary patency rates were compared between the good-to-compromised (≤9 points) and poor (≥10 points) runoff groups, divided according to the modified SVS runoff score. The primary patency rate of the good-to-compromised runoff group was 93.0% at 6 months, 83.3% at 12 months, 75.6% at 24 months, 64.6% at 36 months, and 54.5% at 48 months, whereas that of the poor runoff group was 77.0%, 59.8%, 54.8%, 49.8%, and 41.5%, respectively. The good-to-compromised runoff group (≤9 points) had better patency rates than the poor runoff group (≥10 points) (P=0.011; Fig. 4). The modified SVS scoring system seemed to be more accurate in evaluating patency after SFA angioplasty with stenting than the conventional SVS scoring system.

We confirmed the pulses of the dorsalis pedis and posterior tibial arteries using a portable Doppler device after the procedure. No distal embolization was detected. Seven patients developed insignificant hematomas, three patients had wound infection, and two patients had elevated cardiac enzymes without symptoms. No perioperative deaths occurred.

DISCUSSION

The TASC II classification has guided medical decision making in several institutions since 2000. However, the paradigm has shifted to percutaneous transluminal angioplasty (PTA) with or without stenting as the intervention of choice for all types of infrainguinal lesions. Nitinol-stent-based interventions have been introduced and are beneficial for reducing neointimal proliferation, which is the major cause of restenosis after PTA with or without stenting [20,21].

Recently, a prospective randomized multicenter study was conducted to investigate the use of drug-eluting stents

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and new-generation bare nitinol stents to achieve good patency with PTA [22,23]. However, this needs to be investigated in SFA cases. It is essential to identify the factors that influence the efficacy of interventions after SFA angioplasty with nitinol stenting for the prediction of primary patency. Clinically, factors such as diffuse atherosclerotic cardiovascular disease, threatened limb loss, diabetes mellitus, and chronic kidney impairment requiring dialysis have been shown to negatively influence the long-term patency of limbs undergoing PTA with or without stenting. Technically, lesion length, plaque morphology, and poor post-PTA appearance due to the degree of residual stenosis have been shown to affect the outcome after PTA [6,24].

We selected primary patency, as defined by the SVS guidelines, as the indicator for the outcome measure after SFA angioplasty, as it is a widely used and objective indicator for comparing the different endovascular procedures and the effect of risk factors on stent failures [8]. Runoff, as defined by the SVS guidelines, has been applied with different scoring methods to evaluate patency. One method is by simply using the numbers of infrapopliteal patent vessels, which are scored as 0, 1, 2, and 3. Accordingly, patients are categorized into the poor (zero or one vessel) and good (two or three vessels) runoff groups. This method is simpler to apply than other scoring systems; however, the efficacy of this counting system is questionable. The other method is the modified SVS scoring system, which is more complicated because the assessment is based on the degree of disease severity. The initial modified scoring systems according to SVS particularly focus on anatomical lesions. Thus, other types of scoring systems have been developed to reflect clinical factors. Some authors developed new scoring systems with the goal of using the FeDCLIP (female, diabetes, dialysis, critical limb ischemia, lesion length >150 mm, and poor runoff) score (in which the total score ranges from 0 to 7 points, and scores of 0-2, 3-4, and ≥5 points indicate low, moderate, and high risk, respectively) as the clinical indicator. Their primary patency rates were 85.7%, 77.3%, and 74.2% in the low-risk group and 53.0%, 24.3%, and 20.8% in the high-risk group at 1, 3, and 5 years, respectively. Significant differences in primary patency were observed among the three risk groups (P<0.001) [25]. However, clinical indicators have numerous variants, and a previous study showed that sex does not significantly affect the durability of angioplasty of the peripheral vessels [11]. Some promising novel methods have been reported; however, a general consensus on their efficacy has not been reached because of the lack of large-scale multicenter studies and the limited available data [25].

Other studies have suggested that nitinol stenting with angioplasty improved the primary patency of infrainguinal lesions with runoff vessels [11,26]. In particular, SFA nitinol stenting prevented restenosis, as assessed with sonographic imaging, compared with balloon angioplasty [27]. However, the relationship between infrapopliteal vessel patency and stent durability has not been analyzed [28]. Johnston et al. [10] found that the success of endovascular interventions is significantly related to the runoff status. Abando et al. [11] showed that the quality of runoff vessels is useful for deciding the timing of catheter-based procedures (HR 2.54, P<0.001). Consistent with these findings, Ihnat et al. [12] demonstrated that the runoff score significantly affects the primary patency (HR 2.59, P=0.024). In contrast, Lee and Katz [8] and Wilson et al. [13] reported that runoff and primary stent patency are not related to each other in bare nitinol stenting. Thus, distal runoff does not seem to influence the overall stent patency outcomes. In the point of view of the modified SVS score, several studies have investigated the association between primary patency and modified SVS score. Lee and Katz [8] showed no correlation between primary patency and runoff status using the modified SVS runoff scoring system (P=0.79). However, some authors reported that the duration of freedom from re-angioplasty remained the same despite worsening runoff scores (66%±8%, 68%±7%, and 68%±10% for runoff score categories of good, compromised, and poor, respectively) [9]. Our results showed that the runoff status according the modified SVS scoring system influenced the outcome after SFA stenting. With respect to the runoff scores, patients with low scores had better patency than those with high scores, indicating that measurement of the runoff scores may more accurately and prospectively predict the procedural outcomes [2,29].

The TASC II classification has been proven to be a significant predictor of primary patency. In a recent study, the long-term patency and clinical outcomes of nitinol stenting for infrainguinal atherosclerotic disease were investigated using the TASC II classification system, which showed that TASC II C or D lesions had poorer results than TASC II A or B lesions [30]. Our results agree with the findings of this report, as our TASC II A or B cases showed better patency rates than the TASC II C or D cases (P<0.001). The number of infrapopliteal vessels decreased with worsening of the TASC II classification. Interestingly, previous studies found that although the number of patent infrapopliteal vessels decreased as the TASC II classification worsened [8], this was not related to the difference in patency rates between TASC II A or B and TASC II C or D lesions [12]. However, the modified SVS scoring system had an impact on the patency of the poor runoff group (≥10 points).

This study has several limitations. First, we performed a retrospective analysis at a single center. Second, the outcomes according to stent types were not evaluated in this study. Currently, newly developed bare nitinol stents and drug-eluting stents have been frequently used. Thus, further investigations related to this issue are needed. Third, the outcome of the endovascular approach depends on clinical and anatomical factors. Although the scoring systems used are generally accepted, a novel multifactorial scoring system is still needed. Fourth, a total of 17 of the 153 limbs underwent concomitant additional infrapopliteal PTA. However, the limbs did not have any patent crural artery with an SFA lesion. These patients were not classified after the intervention. Fifth, CTA imaging for evaluating the infrapopliteal vessel status and scoring may not be accurate in some cases. However, these were mostly correlated with intraoperative angiography images. Finally, our study lacks a multivariable model to assess the independent associations between runoff vessels and the patency of the SFA stent. Despite the above-mentioned limitations, evaluating the number of runoff vessels using the modified SVS scoring system can indirectly predict the procedural outcomes and patency in patients with claudication.

CONCLUSION

The number of tibial vessels itself does not significantly influence the primary patency rate of the stented SFA. However, the quality of distal runoff vessels measured using the modified SVS runoff scoring system significantly predicts the outcomes after SFA stenting.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHOR CONTRIBUTIONS

Concept and design: BGN, HJJ. Analysis and interpretation: BGN, YMP. Data collection: BGN, JBC, BCL. Writing the article: BGN, HJJ. Critical revision of the article: JBC, BCL, SSL. Final approval of the article: all authors. Statistical analysis: none. Obtained funding: none. Overall responsibility: HJJ.

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