Article published online: 2023-12-04

Technical Success, Midterm Primary Patency, and Factors Affecting Primary Patency of Subintimal Angioplasty Followed by Vasculomimetic Stenting for Trans-Atlantic Intersociety Consensus II C and D Femoropopliteal Arterial Disease—A Prospective Study

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Indian J Radiol Imaging 2024;34:254–261.

Abstract

Background The best option among the endovascular options in long, complex femoropopliteal (FP) lesions, and factors affecting the patency have yet to be well described. There are few studies describing the mid- and long-term patency of endovascular stents in long-segment FP occlusions.

Aim This study aimed to determine the technical success and mid-term patency of subintimal angioplasty with vasculomimetic stenting in Trans-Atlantic Inter-Society Consensus II (TASC) C and D FP disease. The patient and imaging factors that affect primary patency were also analyzed.

Methods and Materials A single-center prospective study was performed on 52 consecutive patients undergoing endovascular treatment for TASC C and D FP disease from 2017 to 2021. Angioplasty with stenting was performed in all patients and followed up for 36 months. Endpoints were primary patency rates and amputation-free survival of the limb. Kaplan–Meier curves were used to see patency rates and amputation-free survival rates.

Results A total of 52 patients underwent stenting with a technical success rate of 100% if the sub-intimal arterial flossing with antegrade-retrograde intervention (SAFARI) technique was used. Primary stent patency at 6, 12, 18, 24, and 36 months was 89.8, 81.4, 76.2, 71.4, and 62.5%, respectively. Amputation-free survival was 98, 95.6, 91.8, and 85.7% at 12, 24, 30, and 36 months, respectively. Cox proportional regression analysis showed smoking and vessel wall calcium score more than 270 degrees as independent predictors of loss of primary patency (hazard ratio 0.35 confidence interval [CI]: 0.003–0.448) and 0.102 (CI: 0.022–0.47), respectively.

Keywords
- peripheral arterial disease
- TASC C and D FP disease
- subintimal angioplasty
- vasculomimetic stent

article published online
December 4, 2023

DOI https://doi.org/10.1055/s-0043-1777015.
ISSN 0971-3026.

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Conclusion Subintimal angioplasty with vasculomimetic stent has good midterm patency in and amputation-free survival in long-segment FP occlusions. Smoking and severe vessel wall calcification adversely affect patency.

Introduction

Chronic limb-threatening ischemia (CLTI), the end-stage form of peripheral arterial disease (PAD), causes significant morbidity and reduced quality of life. Open surgical bypass and endovascular repair remain the treatment options for PAD that is unresponsive to medical treatment. Trans-Atlantic Inter-Society Consensus II (TASC II) recommends open surgical bypass for treating TASC C and D lesions of the femoralpopliteal (FP) arteries.[1] The current 2020 Society of Vascular Surgery (SVS) guidelines also suggest open surgical bypass for long (>20 cm) FP disease in moderate-risk patients.[2] However, due to advances in endovascular techniques and devices, most physicians adopt an endovascular-first approach to these lesions because of the reduced morbidity associated with procedures. Although several studies have demonstrated the superiority of vasculomimetic stents over self-expanding nitinol stents and simple balloon angioplasty in FP lesions, there is a paucity of literature regarding the long-term follow-up outcomes in TASC C and D lesions. Some randomized controlled trials (RCTs) suggest long-term patency of bare-metal stents compared with simple balloon angioplasty. However, none focuses exclusively on long-segment TASC C and D FP disease. The study aimed to analyze the technical success and the medium-term primary patency (36 months) of subintimal angioplasty with stenting in TASC II C and D FP disease. In addition, the clinical and lesion characteristics affecting primary patency were also analyzed.

Materials and Methods

Ours was a single-center prospective study. All patients who underwent endovascular intervention for Rutherford category 4–6 CLTI with FP disease TASC II C and D between January 2017 and March 2021 were included in the study. Patients with TASC II A and B-FP disease and those with a prior infrainguinal arterial bypass were excluded. All the patients included in the study were examined for the presence of diabetes mellitus (fasting serum glucose >110 mg/dL or hemoglobin A1c >7%), hypertension (systolic blood pressure >140 mm Hg or diastolic blood pressure >90 mm Hg), hyperlipidemia (fasting serum cholesterol >200 mg/dL, triglyceride >200 mg/dL, or low-density lipoprotein >130 mg/dL), active smoking, and cardiovascular disease. Preoperative work included lower limb arterial Doppler, ankle brachial pressure index (ABPI), toe brachial index (TBI), and peripheral computed tomographic (CT) angiograms.

CT Angiogram Analysis

The CT angiogram was analyzed for TASC grading, occlusion length, and degree of vascular wall calcification. Axial plane CT images were used to classify the calcium distribution in the peripheral vessel wall. The vessel wall was divided into four sectors in the axial plane, and grading was performed by assessing calcium distribution in one or more of four 90 sectors: grade 0(no calcification), grade 1 (0–90), grade 2 (90–180 degree), grade 3 (180–270 degree), and grade 4 (ring calcification).[3] Superficial femoral artery (SFA) occlusion involving the adductor canal was also analyzed. The quality of infrapopliteal runoff vessels was graded according to the modified SVS guidelines.[4] Infrapopliteal artery scores were multiplied as follows: 0 to 20% stenosis, ×1; 21 to 49% stenosis, ×2; 50 to 99% stenosis, ×2.5; <50% occlusion of vessel length, ×3; and >50% occlusion of vessel length, ×3 with 1 point added. The patients were divided into two groups: good-to-compromised (≤9 points) and poor (≥10 points) runoff groups.

Technique

The procedure was performed by two interventional radiologists with more than 5 years of vascular intervention experience. The contralateral retrograde approach was used in all cases. A 7F 65 cm Balkin modification of the long flexor sheath (COOK Medicals, USA) was used to cross the aortic bifurcation. The subintimal angioplasty was created by making a "Bolia loop" using a 0.035-inch J-tip hydrophilic wire (Terumo, Tokyo, Japan) supported by a 5F-RC (Cook, United States) or 5F Vertebral glide (Terumo, Japan) catheter. Reentry was done by the same catheter used for subintimal passage. In cases where reentry was impossible within 1 cm distal to the occlusion, a retrograde approach was attempted with the pedal access using a 4F sheath and lesion crossed using the subintimal floss technique (SAFARI technique). Angioplasty was performed distal to proximal using a 6 × 10 mm balloon catheter (Advance LP, Cook, Indianapolis, United States). Stenting was performed with a 5.5 mm × 20 cm self-expanding nitinol stent(s) (SUPERA, Abbott) that covered the entire subintimal canal, including entry and reentry points (►**Fig. 1**). In cases which had flush occlusion of SFA, the stent was placed via pedal access to prevent the jailing of profunda in case the stent gets stretched. A 6F pedal access sheath was used using ultrasound-guided access of the posterior tibial or anterior tibial in such cases. Poststenting angioplasty was performed in all cases using 6 × 10 mm balloon (Advance LP, Cook, Indianapolis, United States). In cases of multiple stents, the distal stent was placed first followed by the proximal one. The stent overlap was kept to possible minimum. Intravenous heparin

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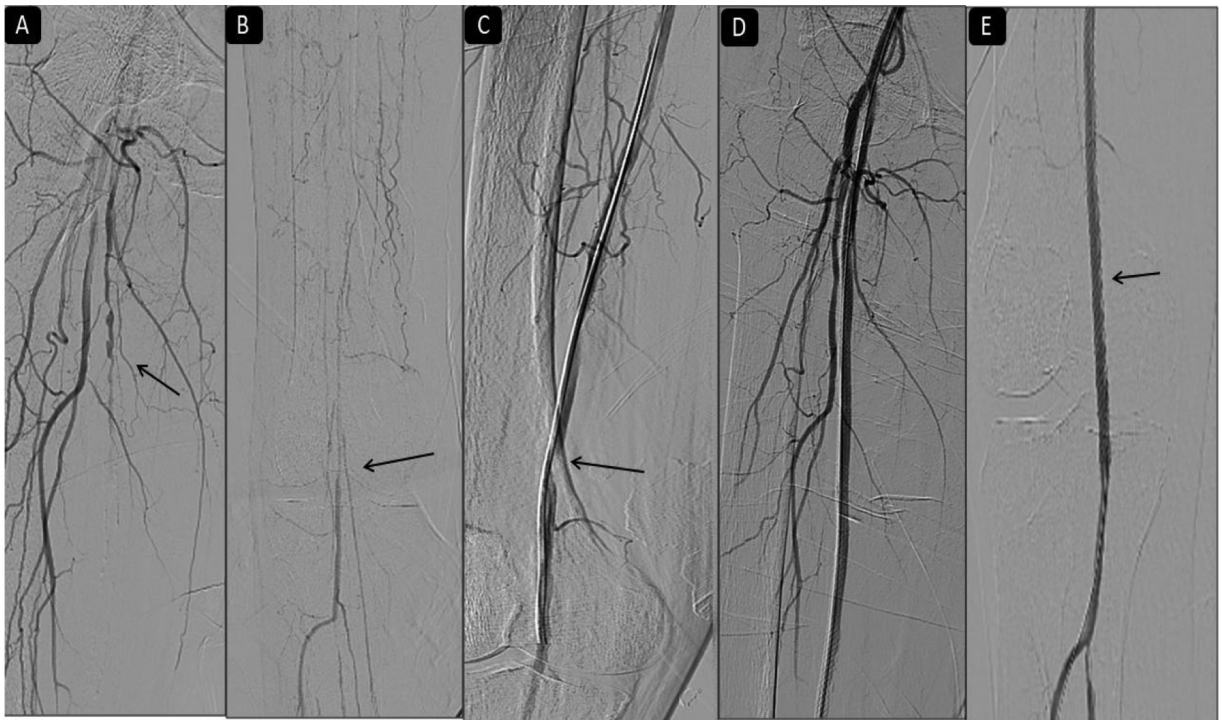

Fig. 1 (**A**) Digital subtraction angiography with left common femoral artery retrograde approach showing Trans-Atlantic Inter-Society Consensus II D disease of right proximal, middle, and distal superficial femoral artery (arrow in A) with reformation (arrow in B) at P1 popliteal artery (**B**). Angiogram after subintimal angioplasty using a 6 mm × 10 cm balloon showed greater than 30% residual stenosis (arrow in C) at the reentry site (**C**). The Supera stent (6mm × 200cm) was deployed, covering the entire occluded segment and reentry site with good flow within (**D** and **E**).

was administered for 48 hours, and the dual antiplatelet agents were continued for 6 weeks and switched to a single antiplatelet agent afterward.

Follow-Up

All patients were followed up with clinical examination, ABPI, TBI, and duplex scan at 6 weeks, 6 months, 1, 2, and 3 years. All patients received proper instructions on how to report if any symptoms occurred in the treated leg before the next follow-up time.

Endpoints

Technical success was defined as crossing the occlusion with residual stenosis less than 30% post-stenting. Loss of primary patency was defined as restenosis of more than 50% within the stent with a peak systolic velocity (PSV) ratio of more than 2.4 in the stent (the ratio between PSV taken at the level of maximum stenosis to the PSV taken at ∼2cm above the stenosis) or stent occlusion with the return of patient symptoms (rest pain or ulcer). Amputation-free survival was defined as freedom from major amputation of the index limb.

Statistical Analysis

The data were analyzed with IBM SPSS Statistics for Windows, Version 26.0. (IBM Corp, Armonk, New York, United States). Kaplan–Meier analysis was used to analyze the event-free survival, and the Mantel-Cox log-rank test was used to compare the factors affecting the primary patency and amputation-free survival. The Cox proportional hazard regression model was used to calculate the hazard ratios of multiple factors affecting primary patency rate and amputation-free survival. Statistical significance was defined as *p*-value less than 0.05.

Results

In the study period, 472 patients underwent invasive treatment for FP disease. After excluding patients with TASC A and B lesions, 52 patients were included in the analysis. Among the study population, 42 were males (80.7%). The risk factors included diabetes 44/52 (84.6%), hypertension 43/52(82.6%), active smoking 17/52 (32.6%), coronary artery disease17/52 (32.6%), and dyslipidemia 7/52(13.2%). Fifteen of fifty-two (28.8%) patients had TASC II C FP disease, while 37 had TASC D lesions. The occlusion length was 21.1 ± 5.8cm (15–33 cm range). Eight patients showed involvement of the P2 segment of the popliteal artery, and 38 patients had adductor canal involvement.

CT calcium grading showed grade 0 in 13/52, grade 1 in 3/52, grade 2 in 13/52, grade 3 in 8/52, and grade 4 in 13/52 patients. Infrapopliteal SVS runoff score was more than 10 (severe)in 12(23%) patients. Thirteen patients had severe disabling claudication pain (who were nonresponders to medical management—Rutherford 3), while 12 had rest pain (Rutherford 4), and 29 had arterial ulcers (Rutherford 5). The patient- and lesion-related characteristics are provided in ►**Tables 1** and **2**.

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Table 1 Patient and lesion characteristics

	Total
Patient number	52
Age, mean (SD)	63.11 (6.02)
Gender, male (%)	42 (80.7%)
ABPI, mean	0.60 (0.04)
Current smoking	17 (32.6%)
Diabetes	44 (84.6%)
Hypertension	43 (82.6%)
CAD	17 (32.6%)
Previous stroke	4 (7.6%)
Hypercholesterolemia	7 (13.4%)
TASC C/D	15 (28.8%)/ 37(71.2%)
Rutherford III/IV/V	13 (24%)/ 12(23.1%)/. 29(55.7%)
Follow-up (months) (SD)	36 median (12–42 months)
Length of occlusion in cm, median(range)	21.1 cm (15–33cm)
Involving adductor canal SFA	38 (73.07%)
SVS runoff score	
<10	40 (77%)
≥10	12 (23%)
Quadrant-wise circumferential calcium score 0.461	
Grade 4 (270–360 degrees)	13 (26%)
Grade 0/1/2/3	13/3/13

Abbreviations: ABPI, ankle brachial pressure index; CAD, coronary artery disease; SD, standard deviation; SFA, superficial femoral artery; SVS, Society of Vascular Surgery; TASC C/D, Trans-Atlantic Inter-Society Consensus II C/D.

Technical Success

Antegrade reentry was achieved in 34/52 patients. In 18 (34.5%) patients in which subintimal reentry was difficult, the SAFARI technique was performed by anterior tibial artery or posterior tibial artery puncture. After using the SAFARI technique, the overall technical success rate was 100%. A single stent was placed in 43 patients. Two overlapping stents, with maximum an overlap of 10 cm (range of overlap 2–10 cm, median: 3.6cm) were placed in nine patients. In five cases that had flush occlusion of proximal SFA, the stents were placed via anterior tibial (3) and posterior tibial (2) access to prevent inadvertent jailing of profunda if the stent elongates. Intraprocedural complications included distal embolism (treated with suction thrombectomy in 4 patients), wire-induced perforation of the collaterals (treated with gel foam embolization in 3 patients), and retrograde approach thrombosis in situ (treated with mechanical thrombectomy in 1 patient).

Stent Patency and Amputation-Free Survival

The mean follow-up time was 27.48 months (range: 12–42 months). There was a significant increase in ABPI 0.5 (0.45–0.67) from pre-procedure values to 0.86 (0.65–0.92) at 6 months follow-up (*t*-test, $p \leq 0.001$). Of the 29 Rutherford V patients, 27 (91%) showed complete ulcer healing from 4 to 12 weeks. Kaplan–Meier survival analysis showed primary stent patency of 90, 81.8, 77.1, 72.3, and 63.3% at 6, 12, 18, 26, and 36 months, respectively. Four of fifty patients underwent major amputation within 3 years. Amputation-free survival was 98, 95.6, 91.8, and 85.7% at 12, 24, 30, and 36 months, respectively (►**Fig. 2**).

Table 2 Subanalysis of ulcer healing of Rutherford V patients after SFA stenting

No of patients	29/52 patients
Ulcer location	
Toe	22/29
Heel of foot	3/29
Dorsum of foot	4/29
Diabetic patients	25/29
Ulcer healing post SFA stenting	27/29
Within 4 weeks	8/29
4–8 weeks	10/29
8–12 weeks	9/29

Abbreviation: SFA, superficial femoral artery.

Factors Associated with Loss of Stent Patency

Cox proportional regression analysis showed active smoking (> 2 cigarettes/day) and grade 4 quadrant-wise calcium scoring (> 270 degrees) as independent risk factors affecting primary patency. The modified SVS value for infrapopliteal outflow more than 10 showed a positive correlation with loss of primary patency; however, it was not statistically significant (p-value = 0.154; ►**Fig. 3**). Risk factors such as diabetes, hypertension, age, male gender, stroke, and coronary artery disease were not associated with loss of patency in the multivariate analysis. The length of occlusion, type of TASC (C or D), number of stents, and involvement of the adductor canal showed no significant association with patency rates (►**Table 3**).

Discussion

Our primary results show that subintimal angioplasty with the placement of a vasculomimetic stent offers high technical success (100%) with good primary patency rate (90, 81.8, 77.1, 72.3, and 63.3% at 6, 12, 18, 26, and 36 months) and amputation-free survival rates(98, 95.6, 91.8, and 85.7% at 12, 24, 30, and 36 months, respectively). Active smoking (> 2 cigarettes/day) and vessel wall severe calcium (> 270 degrees) were independent risk factors affecting primary patency.

Our high technical success rate of 100% in these long-segment FP lesions can be attributed to the use of the subintimal approach and the SAFARI technique (in 34.8% of cases). Our technical success rate without using the SAFARI technique would be 66%, similar to other studies in long-segment FP disease. Montero-Baker et al demonstrated a

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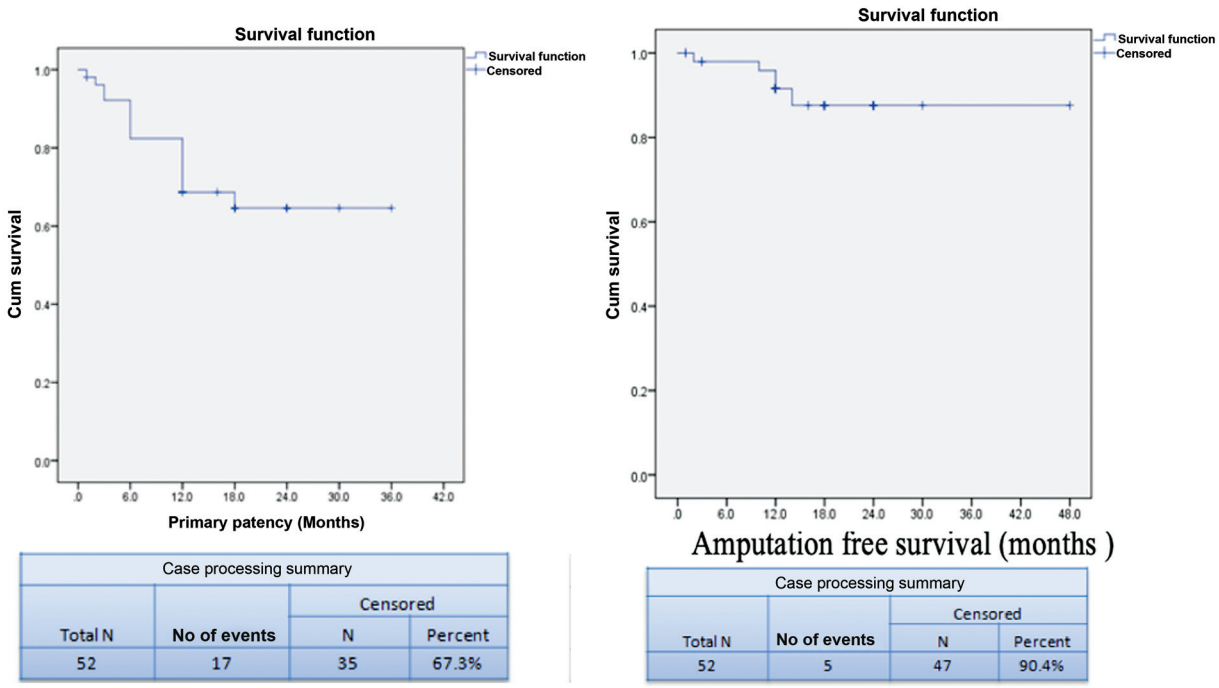

Case processing summary			
		Censored	
Total N	No of events	N	Percent
52	17	35	67.3%

Case processing summary			
		Censored	
Total N	No of events	N	Percent
52	5	47	90.4%

Fig. 2 Kaplan–Meier analysis showing (**A**) primary patency rates and (**B**) amputation-free survival of the study group.

technical success rate of 86% after using the SAFARI technique, comparable to our study.[5] Antusevas et al showed a technical success rate of 87.7% for subintimal angioplasty compared with 81.3% for intraluminal angioplasty.[6]

Our primary patency rates were marginally better than other literature in long-segment SFA lesions. Armstrong et al showed a primary patency rate of 65% for primary nitinol stent placement in long FP lesions with a mean length of 254 ± 58 mm after a follow-up of 1 year.[7] Durabillity-200 study, which analyzed primary stenting with Protégé Ever Flex 200-mm-long self-expanding nitinol stent in TASC C and D lesions (average lesion length of 242 mm), demonstrated a primary patency rate of 64.8% at 1 year.[8] STELLA trial, which demonstrated primary nitinol self-expanding stent (Life

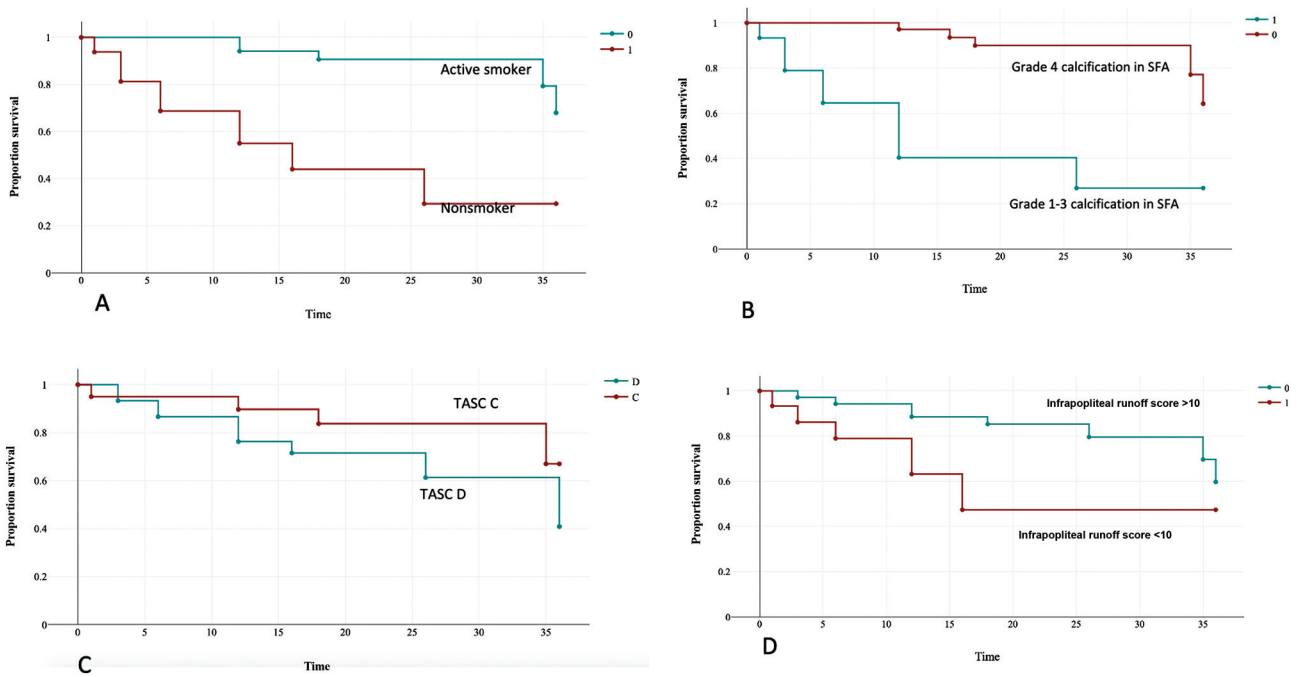

Fig. 3 Log-rank analysis of primary stent patency between (**A**) smokers and nonsmokers, (**B**) grade 4 calcification, and grade 1 to 3 calcification of superficial femoral artery (SFA) (**C**) Trans-Atlantic Inter-Society Consensus II (TASC) D and C (**D**) infrapopliteal Society of Vascular Surgery outflow score more than 10 versus less than 10.

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Table 3 Cox proportional regression analysis showing factors affecting loss primary patency

Variables affecting primary patency	B	Standard error	*p*-Value	Hazard ratio	95% CI for hazard ratio	
					Lower	Upper
Hypertension	1.311	0.787	0.096	3.709	0.793	17.351
Coronary artery disease	−0.730	0.666	0.274	0.482	0.131	1.780
Previous stroke	−1.242	1.106	0.261	0.289	0.033	2.524
Age	−0.069	0.074	0.351	0.933	0.806	1.079
Diabetes mellitus	2.085	1.415	0.141	8.041	0.503	128.664
No smoking versus smoking	−3.363	1.305	0.010	0.035	0.003	0.448
ABPI <0.5	6.318	10.320	0.540	554.519	0.000	–
Rest pain	3.015	1.643	0.067	20.380	0.813	510.674
Ulcer	0.085	1.362	0.950	1.089	0.075	15.717
GLASS GRADE (2 vs. ¾)	−0.761	0.771	0.324	0.467	0.103	2.120
TASC (C vs. D)	0.527	1.1	0.53	1.5	0.200	13.988
Adductor canal involvement	−2.226	1.850	0.229	0.108	0.003	4.058
Length of occlusion (<20 vs. >20 cm)	0.081	0.099	0.411	1.085	0.894	1.316
Modified SVS runoff score (<10 vs. > 10)	−1.139	0.800	0.154	0.320	0.067	1.535
1 stent versus 2 stents	0.16	0.25	0.80	1.17	0.34	4.08
Calcium score (1–3 vs. 4)	−2.282	0.779	0.003	0.102	0.022	0.470
Balloon diameter (5 vs. 6 mm)	1.795	1.295	0.166	6.017	0.476	76.086

Abbreviations: ABPI, ankle brachial pressure index; CI, confidence interval; SVS, Society of Vascular Surgery; TASC C/D, Trans-Atlantic Inter-Society Consensus II C/D.

Stent, for TASC C and D FP lesions, demonstrated a primary patency rate of 68% at 1 year with a stent fracture rate of 17.7%.[9] The higher patency rates in our study can be attributed to the use of self-expanding vasculomimetic interwoven nitinol stents (SUPERA, Abbott systems) compared with the studies using laser-cut nitinol stents. RCT comparing nitinol stenting to bypass surgery for TASC C and D lesions showed that primary and secondary patency at 24 months was 60% in the stent group and 72%, respectively, compared with 56 and 73% in the bypass group ($p = 0.42$ and $p = 0.09$, respectively.[10]

The amputation-free survival rates (98, 95.6, 91.8, and 85.7% at 12, 24, 30, and 36 months, respectively) are comparable to other literature, including the study by Brouillet et al, who showed an amputation-free survival of 95.5% in their study of primary stenting of TASC C and D lesions.[11] Elmahdy et al showed no major amputations after primary stenting of TASC C and D lesions in their study after a mean follow-up of 36 months.[12] Their high limb salvage rate may be due to the smaller mean lesion length of 17 cm in their study compared with our study (20 cm). Enzmann et al showed in their RCT comparing nitinol stenting to bypass surgery for TASC C and D lesions that primary and secondary patency at 24 months was 60 and 72% in the stent group, compared with 56 and 73% in the bypass group ($p = 0.42$ and $p = 0.09$, respectively), without statistical significance.[10] The limb salvage rate in the Enzmann et al study also showed no significant difference between the groups, with 100% in the stent group versus 88% in the bypass group at 2 years.[10] Our amputation-free survival was 98% at 1 year, similar to the Enzmann et al study. Thus, an endovascular first protocol for TASC C and D FP lesions is justifiable. However, long-term follow-up and larger population studies are needed. The BEST-CLI trial also has justified the endovascular approach for long-segment FP lesions if suitable vein grafts are not available.[13]

Among the risk factors, age, gender, diabetes, hypertension, congenital heart disease, and stroke were not associated with loss of primary patency. Lazaris et al also suggested that none of the risk factors of atherosclerosis influenced the primary patency after angioplasty for FP lesions.[14] Although several studies have shown that diabetes is associated with a loss of patency, statistical significance was not established as most of our study population is diabetic.[15] Active smoking (>2 cigarettes/day) was associated with loss of primary patency ($p = 0.01$) with a high hazard ratio. Several studies have shown that smoking is associated with the progression of PAD and it impairs the patency of FP bypass grafts.[16] Elmahdy et al showed that smoking is an independent risk factor for restenosis after angioplasty and stenting for FP disease types C and D.[12]

The lesion length did not affect primary patency in our study. However, a few studies have shown that the occlusion length negatively affects patency rates. Lazaris et al showed that patients with more than 30 cm long lesions showed significantly lower patency compared with the less than 30 cm group.[14] However, the results of the STAR registry indicate no difference in patency between the group with 5 to 10 cm long lesions and the group with more than 10 cm

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lesions.[15] A possible explanation of the lesion paradox might be our population's relatively high mean lesion length(20cm) compared with other study groups. Brouillet et al, in their study, showed higher rates of in-stent restenosis in TASC-D lesions compared with TASC-C (35 and 10%, respectively, $p = 0.005$).[11] However, our study also showed no significant difference in patency rates between the TASC C and D groups.

Studies using laser-cut stents showed reduced patency when the involved adductor canal.[17] This is attributed to mechanical stress on the artery in the adductor canal due to anchoring by the adductor magnus fascia (19). However, in our study, lesions in the adductor canal were not associated with loss of patency, likely due to the use of vasculomimetic stents with higher kink resistance

Existing literature supports the strong association of high circumferential calcium score with acute vascular regurgitation, increased stent use, and a high risk of stent fracture. Our study also confirmed that a 270 to 360-degree circumferential calcium scoring is an independent factor affecting primary patency. Fanelli et al also found a positive correlation between circumferential calcium deposition, decreased drug absorption after DEB angioplasty, and poor patency rates.[3] Since multiple studies show the influence of severe calcification on stent patency, and there is no standardized approach and consensus for quantifying calcium on CT angiography (CTA) and digital subtraction angiography (DSA) (20), there is a need to develop a standardized and dedicated calcium scoring system in CTA and DSA for FP lesions to predict clinical outcomes and guide appropriate treatment.

In our study, the Modified Infrapopliteal SVS runoff score more than 10 positively correlated with loss of primary patency. Davies et al divided patients into three runoff score groups, less than 5 (good), 5 to 10 (impaired), and more than 10 (poor), and found that poor and impaired scores adversely affected primary patency rates.[18] However, in their study, the proportion of TASC-A lesions in the good score group was higher ($p > 0.004$) compared with the other groups. Lee and Katz showed in their study that there was no difference in primary patency after primary stenting between segments with good drainage versus those with impaired drainage. In addition, the runoff value did not affect limb survival ($p = 0.063$).[19] Because studies show conflicting results, a standardized runoff score needs to be developed to aid in selecting appropriate management based on the runoff scores.

Strengths of our study include a prospective design that included standardized protocols during the pre-procedure assessment, the procedure, and follow-up with a relatively good sample size for analysis. Multiple factors, including demographic, radiological, technical and clinical factors, were analyzed regarding primary stent patency. However, our design did not include a randomized control arm of patients undergoing surgical bypass, the current gold standard treatment for long-segment FP lesions. Specialized reentry devices or advanced endovascular options, such as drug-eluting balloons, lithotripsy or atherectomy devices, were not used. The follow-up is for 3 years; thus, factors affecting the long-term patency of stents were not studied.

To conclude, an initial endovascular approach with subintimal angioplasty and stenting using a vasculomimetic stent is an effective and safe option with good midterm patency and amputation-free survival in TASC C and D-FP lesions. The SAFARI technique significantly increases technical success rates, especially in lesions with long segments. Smoking and severe vascular wall calcification are independently associated with loss of primary patency. However, long-term follow-up and more extensive population studies are needed for generalization.

Author Contributions

A.J. was involved in data collection, manuscript preparation, and revision. J.V. helped in concept, manuscript preparation, and final approval. A.A. contributed to manuscript preparation, revision, and final approval. S.K. was involved in manuscript writing and final approval. P.S. was involved in the revision of the manuscript.

Funding

None.

Conflict of Interest

None declared.

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