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ORIGINAL ARTICLE

Factors affecting outcomes after endovascular treatment for femoropopliteal atherosclerotic lesions

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KEYWORDS
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Summary *Background/Objective:* : This study aimed to investigate the outcomes of femoropopliteal interventions in relation to various influencing factors.
Methods: A retrospective review of 243 endovascular procedures for femoropopliteal atherosclerotic lesions on 243 limbs of 197 patients was performed.
Results: In patients with claudication, the TLR free rates at 1-, 3-, and 5-year intervals were 89.1%, 82.2%, and 78.9%, respectively. Amputation-free survival rates in the claudicants at 1-, 3-, and 5-year intervals were 95.3%, 81.1%, and 65.2%, respectively. Freedom from ischemia at 1-, 3-, and 5-year follow-ups was 77.8%, 69.0%, and 61.3%, respectively. In patients with critical limb ischemia, the TLR free rates at 1-, 3-, and 5-year intervals were 91.3%, 87.4%, and 65.4%, respectively, amputation free survival rates were 72.5%, 44.2%, and 36.8%, respectively, and their freedom from ischemia was 64.6%, 63.4%, and 49.7%, respectively. In the multivariate analysis of influencing factors related to freedom from ischemia, renal insufficiency (hazard ratio [HR] 1.623; 95% confidence interval [CI] 0.999—2.636; $p = 0.050$), TASC C/D lesion (HR 1.903; 95% CI 1.151—3.148; $p = 0.012$), and poor tibial runoff (HR 1.770; 95% CI 1.037—3.023; $p = 0.036$) were statistically significant risk factors. TASC C/D lesion and poor tibial runoff were significant risk factors for recurrent or persistent ischemia in claudication ($p = 0.015$) and in critical limb ischemia ($p = 0.05$), respectively.
Conclusion: Endovascular treatment for femoropopliteal atherosclerotic lesions showed acceptable intermediate-term and long-term outcomes. Renal insufficiency, TASC C/D lesions, and poor tibial runoff adversely affected freedom from ischemia.

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1. Introduction

Steno-occlusion of the femoropopliteal artery leads to claudication or chronic critical limb ischemia. During the last few decades, treatment for femoropopliteal steno-occlusive disease has undergone a significant shift towards the implementation of aggressive endoluminal therapy.[1–8] Percutaneous interventions for femoropopliteal occlusive disease are now mainstream and are being performed for claudication and critical limb ischemia.[6–8] Many studies have examined the risk factors associated with different outcomes following the use of endovascular therapy to treat femoropopliteal lesions, and previous studies have reported various results in terms of influencing factors on various endpoints including anatomic, hemodynamic, and clinical outcomes.[9–23] The aim of this study was to investigate the outcomes of femoropopliteal interventions based on clinical endpoints and to identify risk factors associated with poor outcomes. In addition, we compared the outcomes according to proven influencing factors and the severity of ischemia.

2. Materials and methods

A database of patients who underwent endovascular treatment of the femoropopliteal artery between May 2010 and May 2017 was reviewed, and procedures for chronic femoropopliteal atherosclerotic steno-occlusive disease were selected. Patients with Rutherford symptom classification 2 (moderate claudication), 3 (severe claudication), 4 (rest pain), 5 (ischemic ulceration), and 6 (ischemic gangrene) received invasive treatment. Interventions in patients with acute limb ischemia, in-stent restenosis, vascular trauma, popliteal aneurysm, reintervention, procedures for bypass graft, and technical failure were excluded. Additionally, 15 cases involving patients who were lost to follow-up were also excluded from this study. As a result, 243 femoropopliteal endovascular procedures on 243 limbs from 197 patients were included in the study. Angiograms were reviewed in all cases to assess tibial runoff. Pre-procedure runoff was scored according to the modified Society for Vascular Surgery (SVS) criteria whereby a higher score implies worse runoff.

Patients who had a successful endoluminal intervention received dual antiplatelet therapy. Patients underwent routine clinical follow-ups, including ankle–brachial index (ABI) measurement at 1, 3, and 6 months post procedure and every 6 months thereafter. During follow-up, duplex scan or computed tomography (CT) angiography was performed if patients were symptomatic or if non-invasive tests suggested restenosis/occlusion.

Hypertension was defined as the use of antihypertensive medication for high blood pressure or a systolic blood pressure $\geq$140 mmHg and/or diastolic blood pressure $\geq$90 mmHg. Diabetes mellitus was defined as the use of blood glucose-lowering medication and/or a fasting glucose level of $\geq$126 mg/dl. Dyslipidemia was defined as the use of lipid-lowering medication and/or a cholesterol level $>$200 mg/dl and/or LDL-cholesterol level $>$130 mg/dl. Renal insufficiency was defined as serum creatinine level $\geq$1.5 mg/dl or the requirement for renal replacement therapy. We calculated the tibial runoff score from the angiographic results by attributing to the three leg arteries (anterior tibial, posterior tibial, and peroneal arteries) a value between 0 and 3 (0 = normal artery, minimal lesion; 1 = artery permeable with stenosis between 20% and 49% of its diameter; 2 = artery permeable with stenosis between 50% and 99% of its diameter; 2.5 = thrombosed artery of less than 50% of the height of the artery; 3 = thrombosed artery of more than 50% of the height of the artery). The sum of the three values plus 1 was determined to be the tibial runoff score.[24] We considered a good runoff as a score $<$7 and a poor runoff as a score $\geq$7.

Outcome variables included target lesion revascularization (TLR), limb salvage, and amputation free survival, and freedom from ischemia. TLR was defined as any repeat intervention of the target lesion (plus 10 mm proximal and distal to the index device) or surgical bypass of the target vessel performed for re-stenosis or other complications involving the target lesion.[25] Limb salvage was defined as freedom from major amputation (above the ankle).[25] Amputation-free survival was defined as freedom from above-ankle amputation of the index limb or death.[26] Freedom from ischemia was used as a composite endpoint including freedom from recurrent ischemic symptoms and non-healing of wounds. Recurrent ischemic symptom was defined as a decrease of one or greater by the SVS criteria during follow-up.[26,27] Wound healing was defined as complete epithelization of an ischemic wound on the target limb, persistent for at least 14 days according to the consensus definition.[25]

All statistical analyses were performed using SPSS Statistics for Windows, version 21.0 (IBM Co., Armonk, NY, USA). The Kaplan–Meier method with the log-rank test was used to calculate freedom from TLR, amputation-free survival, and freedom from ischemia. The Cox proportional hazards model was used for time-dependent outcomes. The results were reported as the hazard ratio (HR) with 95% confidence intervals (CI). A value of $p < 0.05$ was considered statistically significant.

3. Results

3.1. Patient population and lesion characteristics

Patient characteristics are shown in Table 1. Among 197 patients (80.7% male; age 70.7 $\pm$ 10.6 years, range, 36–90 years), 62.4% had diabetes and the prevalence of renal insufficiency was 25.4%. The severity of disease and anatomic characteristics are shown in Table 2. Among the 243 limbs treated, claudication was the indication for treatment in 48.6% and 51.4% presented with critical limb ischemia (9.1% with rest pain and 42.4% with tissue loss). According to the Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC classification), 21.0% of lesions belonged to category A; 34.2%, category B; 22.2%, category C; and 22.6%, category D. The mean number of patent runoff vessels reaching ankle level was 1.6 $\pm$ 0.9, and the mean tibial runoff score, according to the SVS criteria mentioned above, was 7.0 $\pm$ 1.9. The runoff score of limbs indicated that 37.0% of

Table 1 Patient characteristics (N = 197).

Patient characteristics (N = 197)	
Age (mean ± SD, years)	70.7 ± 10.6
Male	159 (80.7%)
Prevalence of comorbidities	
Diabetes mellitus	123 (62.4%)
Hypertension	144 (73.1%)
Smoking	
Current smoker	72 (36.5%)
Ex-smoker	77 (39.1%)
Ischemic heart disease	
Medical treatment	8 (4.1%)
PCI	20 (10.2%)
Coronary bypass	12 (6.1%)
Stroke	38 (19.3%)
Renal insufficiency	50 (25.4%)

SD, standard deviation; PCI, percutaneous coronary intervention.

Table 2 Lesion characteristics and procedural details (N = 243).

Lesion characteristics	
Classification of ischemia	
Claudication	118 (48.6%)
Rest pain	22 (9.1%)
Tissue loss	103 (42.4%)
TASC classification	
A/B	51 (21.0%)/83 (34.2%)
C/D	54 (22.2%)/55 (22.6%)
Lesion length	
<10 cm	27 (9.9%)
10–20 cm	37 (15.2%)
20–30 cm	66 (27.2%)
≥30 cm	113 (46.5%)
Tibial runoff	
Patent runoff no.	1.6 ± 0.9
>1	124 (51.0%)
≤1	119 (49.0%)
Runoff score	7.0 ± 1.9
<7	90 (37.0%)
≥7	153 (63.0%)
Procedural details	
Concomitant procedure	
Iliac angioplasty	74 (30.5%)
BTK angioplasty	93 (38.3%)
Femoropopliteal procedures	
Type of intervention	
Plain balloon angioplasty	115 (47.3%)
BMS after plain balloon angioplasty	60 (24.7%)
DCB	56 (23.0%)
BMS after DCB	4 (1.6%)
DES	3 (1.2%)
Supera stent	3 (1.2%)
Atherectomy	2 (0.8%)
Type of lesion passage	
True luminal angioplasty	190 (78.2%)
Subintimal angioplasty	53 (21.8%)

BTK, below-the-knee; BMS, bare metal stent; DCB, drug-coated balloon; DES, drug-elluting stent.

cases were associated with good runoff (score <7) and 63.0% with poor runoff (score ≥7).

3.2. Procedural details and immediate hemodynamic change

In terms of procedural details, iliac angioplasty and below-the-knee (BTK) angioplasty as a concomitant procedure were performed in 30.5% and 38.3% of cases, respectively. A 1.5–3.0 mm-sized plain balloon was used in all cases of BTK balloon angioplasty. For angioplasty of the femoropopliteal artery, a plain balloon was used in 175 limbs (72.0%), and a bare metal stent (BMS) was required in 60 limbs (24.7%) because of residual stenosis or flow-limiting dissection after plain balloon angioplasty. A drug-coated balloon (DCB) was used in 60 limbs (24.6%), and a BMS was required in 4 limbs (1.6%) after a DCB. For the passage of lesions, subintimal angioplasty was needed in 53 limbs (21.8%). The details of the procedures are shown in Table 2. Immediately after the procedures, ischemic symptoms improved in 85.2% of patients. However, 12.8% of patients did not show improvement and symptom deterioration was observed in 2.1%. The mean ABI change in patients immediately after procedures was +0.34 ± 0.22, and 78.2% of patients showed an increase in ABI of more than 0.15 (Table 3).

3.3. Intermediate and long-term outcomes

The outcomes in terms of TLR-free rate, amputation-free survival rate, and freedom from ischemia are shown in Figs. 1 and 2. In the patients presenting with claudication, the median duration of follow-up was 21.1 ± 19.7 months (range, 0.3–86.7). The TLR free rates in claudicants at 1-, 3-, and 5-year were 89.1%, 82.2%, and 78.9%, respectively. For these patients, amputation free survival rates at 1-, 3-, and 5-year were 95.3%, 81.1%, and 65.2%, respectively. Furthermore, freedom from ischemia was 77.8%, 69.0% and, 61.3% at 1-, 3-, and 5-year, respectively (Fig. 1). In patients presenting with critical limb ischemia, the median duration of follow-up was 21.4 ± 18.4 months (range, 0.2–79.6). The TLR free rates in patients with critical limb ischemia at 1-, 3-, and 5-year were 91.3%, 87.4%, and 65.4%, respectively, their amputation free survival rates were 72.5%, 44.2%, and 36.8%, respectively, and their freedom from ischemia was 64.6%, 63.4%, and 49.7%, respectively (Fig. 2). In multivariate analysis of the influencing factors for freedom from ischemia after intervention using the Cox proportional hazards model, renal insufficiency (HR 1.623; 95% CI 0.999–2.636; p = 0.050), TASC C/D lesion (HR 1.903; 95% CI 1.151–3.148; p = 0.012), and poor tibial runoff (HR 1.770; 95% CI 1.037–3.023; p = 0.036) were statistically significant risk factors (see Table 4).

3.4. Outcomes in relation to influencing factors and severity of ischemia

Figures 3–5 show the freedom from ischemia in the different groups stratified by severity of ischemia (Group A,

Table 3 Immediate post-procedure outcome.

Variables		Percentage
Symptom relief	Improved	85.2%
	No change	12.8%
	Deterioration	2.1%
Hemodynamic change	Change in ABI	
	$\geq$0.15	78.2%
	<0.15	21.8%

ABI, ankle–brachial index.

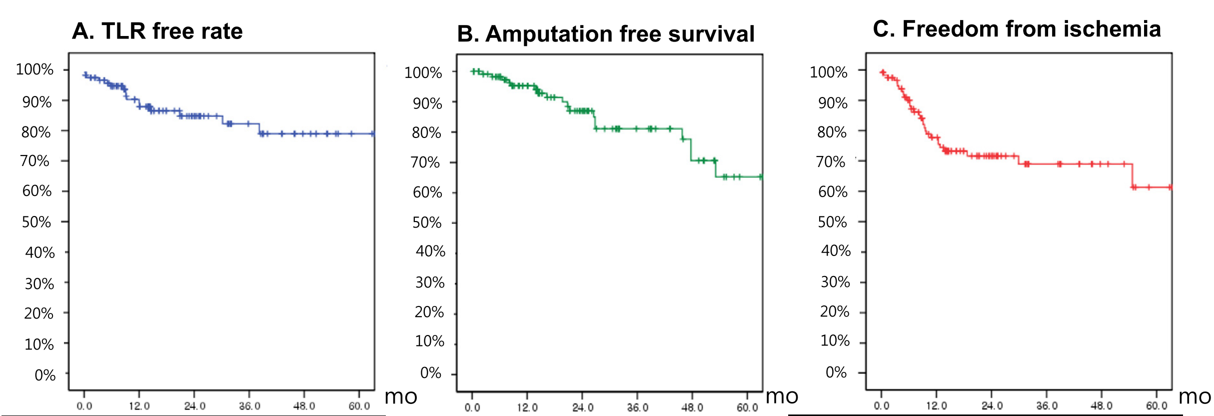
claudication; Group B, critical limb ischemia) according to the presence of each of the influencing factors. Renal insufficiency, TASC C/D lesion, and poor tibial runoff adversely affected outcomes both in claudication and in critical limb ischemia. The presence of a TASC C/D lesion was proven to be a significant risk factor for recurrent or persistent ischemia in claudication ($p = 0.015$) and poor tibial runoff in critical limb ischemia ($p = 0.05$).

4. Discussion

Endoluminal treatment has been performed as a first-line therapy for decades because of its non-invasiveness, technical feasibility, and extremely low mortality rate compared to bypass surgery.[6–8] The long-term outcomes after endovascular treatment of a femoropopliteal lesion have been reported in several studies, and the use of this treatment is still increasing despite the low patency rate, especially in TASC C/D lesions.[11,12,14,18,27] New generation devices are rapidly replacing classical devices, and progress in endovascular techniques has increased the technical success rate in anatomically challenging lesions.[28] Despite technological progress and the widespread use of endovascular therapy in femoropopliteal lesions, outcomes after endovascular therapy are still affected by numerous clinical factors, resulting in varying clinical outcomes. In this study, the overall outcomes after femoropopliteal intervention and the outcomes in relation to influencing factors were investigated.

This paper adds value in that it is based solely on an Asian population. The characteristics of the Asian population including comorbidity, body habitus, and vessel size can affect the outcomes of endovascular treatment. Multiple studies have shown racial disparities of cerebrovascular disease and stroke.[29–32] There are also reports regarding racial differences in the practice and outcomes of endovascular treatment or bypass surgery for peripheral arterial disease.[33–36] According to recent analyses of Medicare and Nationwide Inpatient Sample data, individuals of African origin and Hispanics with peripheral arterial disease are more likely to undergo amputation and less likely to be offered lower extremity arterial revascularization or to undergo aggressive surgical therapy for limb salvage than non-Hispanic Caucasians.[37–40] These disparities have been attributed to not only ethnic difference but also differences in socioeconomic status, access to care, insurance status, and/or severity of the disease.[38] All of these factors affect the practice and results of treatment, so they must be considered in understanding of treatment outcomes. In Korea, reimbursement of the device is government controlled with a diagnosis-related group-based payment. The prices are generally lower and registrations of foreign devices are relatively slow. Differences in features of medical system as well as ethnic characteristics in Korea might influence the choice of treatment modality and clinical outcomes.

Comparing intermediate to long-term outcomes, the critical limb ischemia group showed lower amputation free survival rates and freedom from ischemia than the claudication group. The 5-year amputation free survival rates and freedom from ischemia in critical limb ischemia were less than 50%, representing the limitation of efficacy in maintaining long-term outcomes. Otherwise, the 5-year outcomes of amputation free survival rates and freedom from

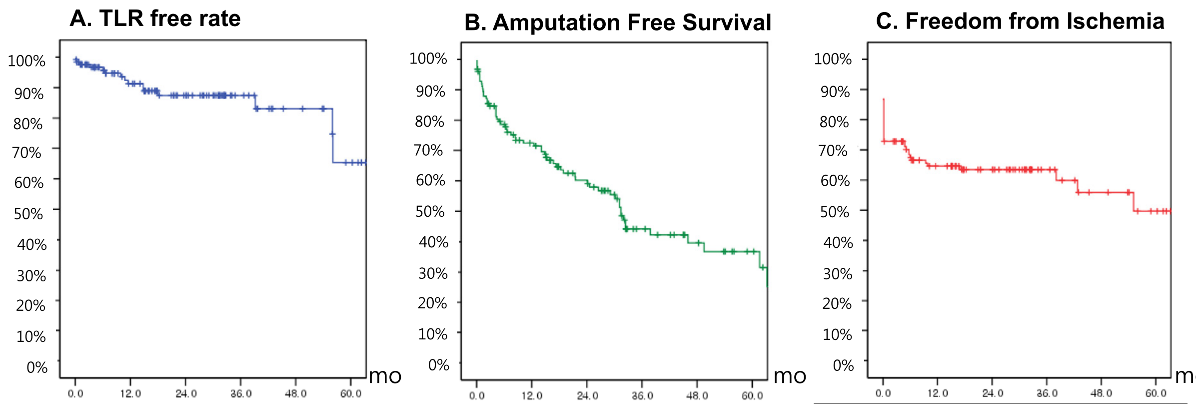


A. TLR free rate	1-yr	3-yr	5-yr
# at risk	76	25	6
# of event	11	4	1
KM estimate	89.1%	82.2%	78.9%

B. Amputation free survival	1-yr	3-yr	5-yr
# at risk	85	31	8
# of event	5	9	4
KM estimate	95.3%	81.1%	65.2%

C. Freedom from ischemia	1-yr	3-yr	5-yr
# at risk	70	20	5
# of event	23	6	1
KM estimate	77.8%	69.0%	61.3%

Figure 1 Outcomes from intervention on femoropopliteal artery in patients with claudication ($N = 118$).



A. TLR free rate

	1-yr	3-yr	5-yr
# at risk	80	23	5
# of event	9	3	3
KM estimate	91.3%	87.4%	65.4%

B. Amputation Free Survival

	1-yr	3-yr	5-yr
# at risk	78	24	7
# of event	33	24	3
KM estimate	72.5%	44.2%	36.8%

C. Freedom from Ischemia

	1-yr	3-yr	5-yr
# at risk	65	20	6
# of event	43	1	3
KM estimate	64.6%	63.4%	49.7%

Figure 2 Outcomes from intervention on femoropopliteal artery in patients with critical limb ischemia (N = 125).

ischemia in patients with claudication were relatively high and acceptable. Endovascular treatment of critical limb ischemia has value because of its low operative risk, high technical success, short-term efficacy, and expected poor patient survival. The minimal peri-procedural risk with high technical success on frail, comorbid patients may compensate for poor long-term outcomes. However, it seems evident that even with the progress in endovascular technology, outcomes in critical limb ischemia in relation to treatment durability still have an evident weak point, and the effect on a patient's long-term outcome is limited. Further research is needed about the effect of more liberal stent use or more aggressive therapy including atherectomy on outcomes in critical limb ischemia.

Black et al showed that insulin-dependent diabetes, poor runoff in the foot, and renal insufficiency were predictive of endoluminal failure after infrainguinal intervention.[41] In addition, limb-threatening ischemia as the indication for treatment is most highly associated with failure of both primary patency and secondary patency.[42] It was suggested that multilevel intervention and those associated with tibial intervention have inferior outcomes than single level intervention.[42] In our study, renal insufficiency, TASC C/D lesion, and poor tibial runoff were statistically significant risk factors for recurrent or persistent ischemia, and all of these showed trends associated with poor outcomes, both in claudication and in critical limb ischemia.

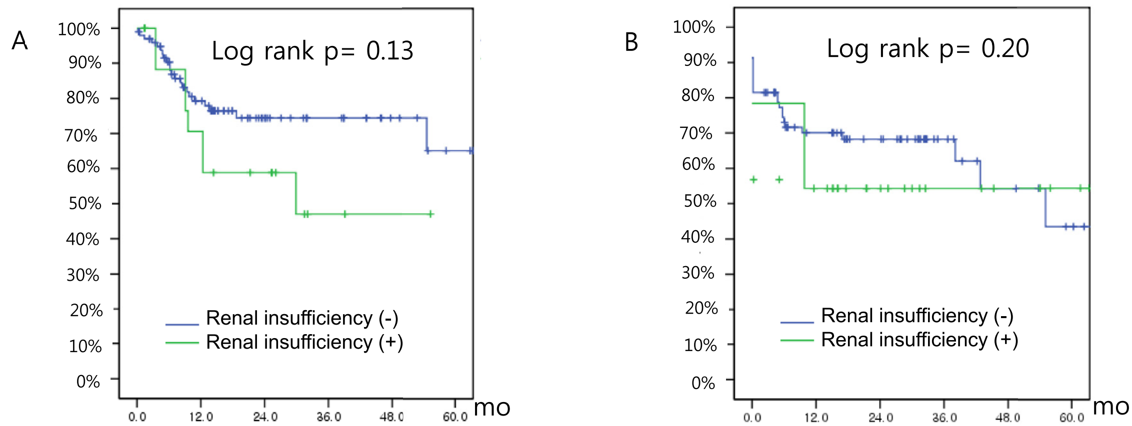
Table 4 Factors affecting freedom from ischemia after femoropopliteal artery intervention (N = 243).

	p	HR (95% CI)
Renal insufficiency	0.050	1.623 (0.999–2.636)
Critical limb ischemia	0.352	1.255 (0.778–2.027)
TASC C/D	0.012	1.903 (1.151–3.148)
SIA	0.279	0.725 (0.405–1.298)
Stent insertion	0.138	1.428 (0.892–2.286)
Runoff score $\geq$7	0.036	1.770 (1.037–3.023)

SIA, subintimal angioplasty.

Renal insufficiency has been reported to affect the endovascular lesion itself by promoting calcification and progression to BTK. Even though several different definitions of renal insufficiency were used, it has been shown to have an adverse effect in percutaneous intervention and open revascularization.[43] The presence of a TASC C/D lesion was associated with poor outcomes after endovascular intervention. However, although the limitations of endovascular treatment in TASC C/D lesions are well recognized, the treatment modality is often still chosen irrespective of patency or ischemia recurrence. Tibial runoff has been an important issue in many reports with regard to both endoluminal treatment and open surgery.[26,44–48] There are studies examining the ability of runoff score to predict hemodynamic success and graft patency.[49–51] These studies have shown that the outcomes of distal bypasses are dependent on the inflow, venous conduit, and distal runoff. The better outcomes after femoral artery intervention were demonstrated in low runoff scores rather than in high runoff scores.[44] Recently, because of the development of endovascular devices and advances in technology, endoluminal treatment of tibial vessels is increasing. Therefore, further studies on the efficacy and indication of treatment for BTK lesions in femoropopliteal intervention are required.

This study has several limitations. First, we could not investigate the primary patency of the target lesions after intervention as our follow-up protocol was based on clinical symptoms, signs, and hemodynamic data. Only an extremely small number of patients received duplex scans or CT angiography during the follow-up period. Even though the hemodynamic data was highly indicating the patent treated vessels, we could not specify the patency data by the definition of patency recommended in reporting guidelines. Second, there was a lack of specific data regarding the management of tissue loss. Wound healing



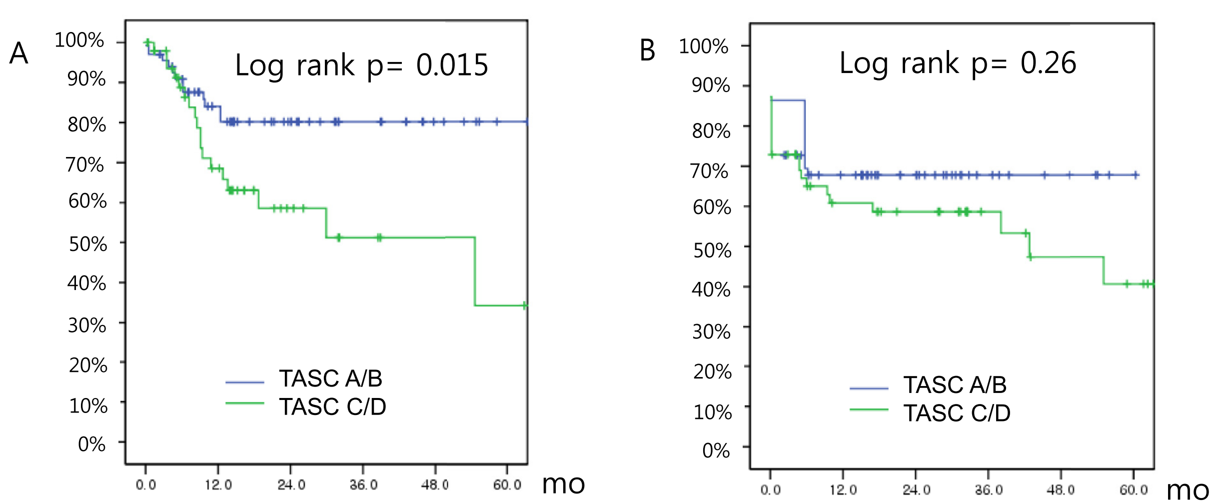
	1-yr	3-yr	5-yr
Renal insufficiency (-)	58	18	5
Renal insufficiency (+)	12	2	0

	1-yr	3-yr	5-yr
Renal insufficiency (-)	44	13	3
Renal insufficiency (+)	21	7	3

Figure 3 Freedom from ischemia according to the presence of renal insufficiency in patients with claudication (A) and critical limb ischemia (B) (The number of limbs at risk at each time interval is shown *below* the figure).

and tissue loss depends on numerous factors including ischemia, infection, accessibility to medical services, patient preference, and physician's intension or policy. We defined the wound healing as complete epithelization of an ischemic wound of a target limb persistent for at least 14 days, according to the consensus definition. However, we expect that the achievement of this criteria was affected by not only the result of revascularization, but also various other factors. Third, the sample size was not big enough for conclusive results and the data from several different treatment types were mixed. The population of this study was heterogeneous, and various types of treatments are currently being performed in this endovascular era. Our study was based on the data of a mixed population receiving mixed treatments; therefore, it has only limited statistical power.

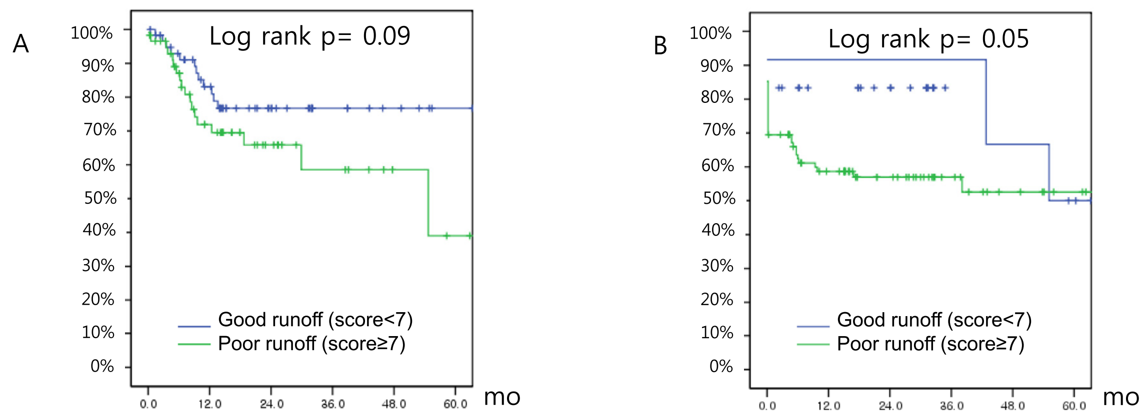
In conclusion, endovascular treatment for femoropopliteal atherosclerotic lesions showed acceptable intermediate and long-term outcomes. However, the critical limb ischemia group showed lower amputation free survival rates and freedom from ischemia than claudication group. Renal insufficiency, TASC C/D lesion, and poor tibial runoff adversely affected freedom from ischemia.



	1-yr	3-yr	5-yr
TASC A/B	44	15	3
TASC C/D	26	5	2

	1-yr	3-yr	5-yr
TASC A/B	37	9	1
TASC C/D	28	11	5

Figure 4 Freedom from ischemia according to the TASC classification in patients with claudication (A) and critical limb ischemia (B) (The number of limbs at risk at each time interval is shown *below* the figure).



	1-yr	3-yr	5-yr
Good runoff (score<7)	40	12	4
Poor runoff (score≥7)	30	8	1

	1-yr	3-yr	5-yr
Good runoff (score<7)	20	5	2
Poor runoff (score≥7)	45	15	4

Figure 5 **Freedom from ischemia according to the runoff score in patients with claudication (A) and critical limb ischemia (B)** (The number of limbs at risk at each time interval is shown *below* the figure).

Authorship

Ui Jun Park: data collection, data analysis, preparation of manuscript

Hyoung Tae Kim: data collection

Young-Nam Roh: study design, data collection, data analysis, data interpretation, preparation of manuscript, literature analysis.

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Conflicts of interest

The authors declare no conflict of interest.

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