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Comparison between intermittent claudication *versus* chronic limb-threatening ischemia in peripheral arterial disease: a retrospective multicenter cohort study

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Purpose: The anatomical distribution, characteristics of lesions, and treatment modalities for peripheral artery disease (PAD) are diverse. Endovascular intervention is popular for symptomatic PAD, for both intermittent claudication (IC) and chronic limb-threatening ischemia (CLTI). We aimed to investigate the endovascular devices used by comparing patients with PAD referred for endovascular revascularization with IC and CLTI.
Methods: We identified 736 patients with PAD enrolled in the multicenter PAD registry in South Korea from 2019 to 2022. Of these patients, 636 received endovascular treatment at the time of this study. After excluding missing data, we analyzed 506 patients with IC or CLTI. Patients' characteristics, target lesions, and endovascular device data such as type, length, balloon diameter, and stent, were examined. Procedure outcomes of the aortoiliac, femoropopliteal, and below-the-knee lesions were analyzed.
Results: Patients with CLTI were more likely to have diabetes mellitus, below-the-knee interventions, and multilevel PAD than the IC group. Patients with IC had more aortoiliac artery lesions and underwent atherectomies than the CLTI group (63.3% and 61.1% *vs.* 39.7% and 40.6%, respectively; P < 0.001). In patients with femoropopliteal lesions, those with CLTI were more revascularized with stents than the patients with IC, without significant differences (35.3% *vs.* 29.1%, P = 0.161). Compared to the IC group, the CLTI patients showed significantly worse rates of primary patency, amputation, and mortality (P = 0.029, P < 0.001, and P < 0.001, respectively).
Conclusion: Among Korean patients with PAD, there is a significant difference in baseline and lesion characteristics, endovascular strategies, and short-term follow-up outcomes among those with IC and CLTI.
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Key Words: Chronic limb-threatening ischemia, Endovascular procedures, Intermittent claudication, Peripheral arterial disease

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INTRODUCTION

Peripheral artery disease (PAD) is a prevalent condition that affects millions of people worldwide, exhibiting a wide range of clinical presentations from asymptomatic cases to chronic limb-threatening ischemia (CLTI), which carries a substantial risk of limb loss and mortality [1,2]. Despite the increased cardiovascular risks and mortality rates associated with PAD, patients often remain undertreated, and treatment approaches tend to vary across countries [2,3]. To establish optimal management approaches for these patients, it is essential to comprehend the disparities in anatomic distribution, lesion characteristics, and treatment strategies between intermittent claudication (IC) and CLTI. However, there is a scarcity of standardized criteria and independently adjudicated data on angiographic and procedural characteristics derived from real-world clinical registries.

Endovascular interventions frequently serve as the initial choice for patients with symptomatic PAD, whether they present with claudication or CLTI, despite receiving medical therapy [4-6]. Therefore, this study aimed to compare the angiographic distribution of PAD, lesion characteristics, endovascular treatment strategies, and post-procedural outcomes between patients with IC and CLTI who underwent endovascular revascularization. Our findings may provide useful insights into the optimal management of PAD based on disease severity, supporting the development of future clinical trials and treatment strategies.

METHODS

Study population and data collection

In this retrospective study, we had data from the DAMOEUM multicenter registry involving 16 participating Korean centers from April 2019 to August 2022 (Supplementary Table 1). Each site obtained informed consent and received approval from their respective Institutional Review Boards (SNUH IRB No. 2007-141-1143), with a notable feature of the registry being the rigorous on-site data audit, entry of procedure records, and verification performed by the study staff. Risk factors, comorbid disease conditions, laboratory data, medications, and procedural information were entered into the online data site hosted at the Korean Society for Vascular Surgery (KSVS).

This study included 636 cases of endovascular revascularization from the available 736 patients in the DAMOEUM registry at the time of this study, with 95 patients having undergone open surgery and 636 having received endovascular treatment (Fig. 1).

Definitions and outcome variables

To establish the basis for analysis, patients were categorized into 2 groups based on their Rutherford Classification: IC group (Rutherford 1–3) and CLTI group (Rutherford 4–6). The study examined the baseline clinical characteristics, location of endovascular interventions, and procedural characteristics for each group. Baseline characteristics encompassed demographics, comorbid conditions, smoking status, and clinical variables (ankle-brachial index [ABI], claudication distance, Walking Impairment Questionnaire [WIQ] score, and laboratory variables). The arterial anatomy of the target limb was divided into 3 levels: aortoiliac (AI), femoropopliteal (FP), and below-the-knee (BTK) (Fig. 2). Multilevel disease was defined as the presence of angiographically significant (>50%) luminal stenosis in 2 or more arterial levels in the target limb. Lesion characteristics included anatomical grading TransAtlantic InterSociety Consensus (TASC) [7], *de novo* lesion status, and calcification grade.

The study examined several outcomes, including procedural success, defined as the successful treatment of the lesion with ≤30% residual stenosis and without complications. Primary endpoints focused on 6-month major adverse limb events (MALEs) and primary patency. MALE was defined as

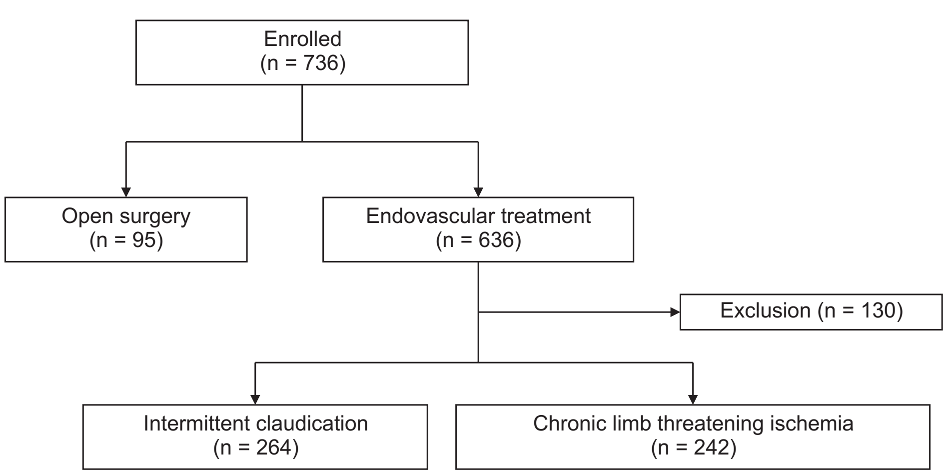

Fig. 1. Flow chart for distribution of enrolled patients.

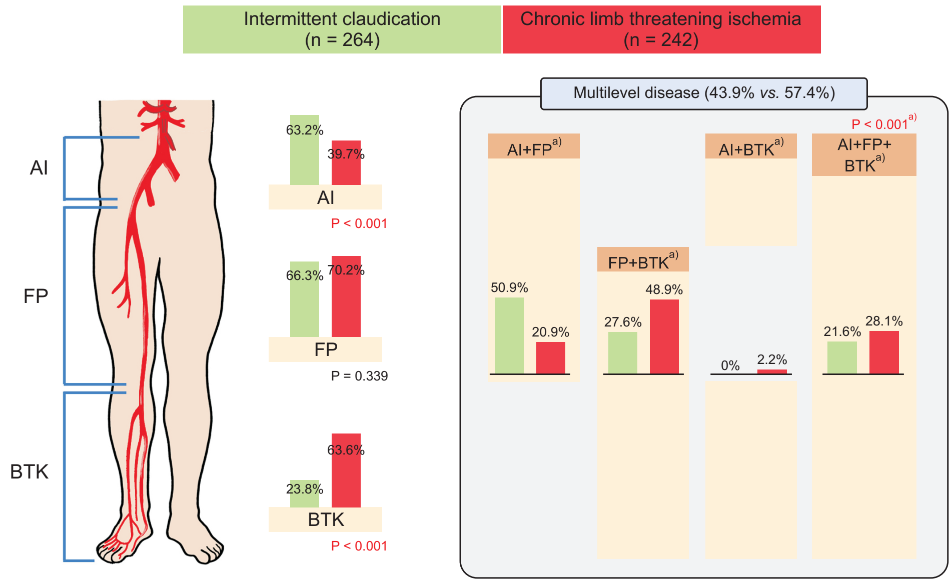

Fig. 2. Lesion distribution of peripheral artery disease. AI, aortoiliac; FP, femoropopliteal; BTK, below-the-knee. [a]P < 0.001, statistically significant.

a composite outcome involving all-cause death, target lesion or vessel revascularization (TLR or TVR) (endovascular or surgical), or major target limb amputation. Secondary endpoints evaluated assisted primary patency and secondary patency.

In this study, patency was defined as the presence of one or more of the following items during post-procedure follow-up: (1) when imaging tests such as ultrasound, CT, MRI, or angiography show smooth blood flow without any signs of stenosis or occlusion or with less than 50% stenosis within the 5-mm borders adjacent to the target lesion; (2) if the pulse is palpable after the procedure; or (3) when the ABI increases by more than 0.15 or the pulse volume recording waveform increases by more than 50%. Primary patency refers to patency that is obtained without the need for additional or secondary surgical or endovascular procedures, or the interval from the time of the original intervention until any intervention designed to maintain or reestablish patency is performed. Secondary patency is patency obtained with the use of an additional or secondary surgical or endovascular procedure after occlusion occurs.

TLR/TVR were defined as any reintervention within the target lesions/vessels due to symptoms and stenosis of more than 50% or occlusion on angiography. A major amputation is defined as any procedure that results in amputation at the level of the ankle or above of affected limb.

Statistical analyses

Data were analyzed using the IBM SPSS Statistics ver. 26.0 (IBM Corp.). Continuous variables were reported as mean ± standard deviation and compared using the t-tests, while categorical variables were presented as numbers (percentage) and compared using the chi-square tests. A Kaplan-Meier analysis was employed to compare follow-up outcomes between the 2 groups; both unadjusted and adjusted analyses were performed. Multivariable Cox regression analysis was utilized to study 6-month outcomes while adjusting for baseline patient characteristics, such as age, sex, diabetes mellitus (DM), chronic kidney disease (CKD), and cardiac disease. The threshold for statistical significance was set at $P < 0.05$.

RESULTS

Clinical characteristics

After excluding 130 patients with missing data, the final analysis included 264 patients with IC and 242 with CLTI. Baseline characteristics revealed that the mean age of overall patients was 71.4 ± 16.9 years, with no significant difference between the groups (Table 1). Male constituted the majority of the patients (83.0%), being more frequent in the IC group than in the CLTI group (86.7% *vs.* 78.9%, P = 0.026). The CLTI group had a higher prevalence of DM (46.6% *vs.* 62.8%, P < 0.001) and CKD (23.1% *vs.* 37.6%, P < 0.001), whereas the IC group had a higher rate of hyperlipidemia (55.3% *vs.* 43.4%, P = 0.008) and current smoker (37.5% *vs.* 26.0%, P = 0.003). Laboratory values indicated that patients with CLTI had significantly higher levels of WBC, ESR, and high sensitivity CRP (hs-CRP), indicating a higher level of inflammation, and lower levels of estimated glomerular filtration rate in the IC group. In contrast, patients with IC had significantly higher levels of total cholesterol, TGs, and LDL. The lower extremity symptoms including claudication of each group were also investigated and analyzed, and detailed symptoms of rest pain and wounds in the CLTI group are presented in Supplementary Table 2.

Lesion characteristics

A total of 825 target vessels in 506 limbs were treated with

Table 1. Comparison of clinical data between patients with IC and CLTI undergoing endovascular treatments

Characteristic	Total	IC group	CLTI group	P-value
No. of patients	506	264	242	
Age (yr)	71.4 ± 16.9	70.9 ± 21.2	71.9 ± 10.2	0.497[a)]
Sex, male:female	420:86 (83.0)	229:35 (86.7)	191:51 (78.9)	0.026[b)]*
Body mass index (kg/m^2)	23.5 ± 8.4	23.4 ± 3.0	23.5 ± 11.8	0.881[a)]
Comorbidity	499 (98.6)	260 (98.5)	239 (98.8)	>0.999[b)]
Diabetes melliuts	275 (54.3)	123 (46.6)	152 (62.8)	<0.001[b)]*
Hypertension	379 (74.9)	197 (74.6)	182 (75.2)	0.981[b)]
CKD[c)]	152 (30.0)	61 (23.1)	91 (37.6)	<0.001[b)]*
Hyperlipidemia	251 (49.6)	146 (55.3)	105 (43.4)	0.008[b)]*
Cardiac disease	144 (28.5)	69 (26.1)	75 (31.0)	0.209[b)]
Lung disease	20 (4.0)	8 (3.0)	12 (5.0)	0.252[b)]
Smoking				0.003[b)]*
Non-smoker or quit >10 yr	274 (54.2)	136 (51.5)	138 (57.0)	
Previous smoker, quit <10 yr ago	60 (11.9)	22 (8.3)	38 (15.7)	
Current smoker	162 (32.0)	99 (37.5)	63 (26.0)	
Medication				
Antiplatelet agent	338 (66.8)	183 (69.3)	155 (64.0)	0.166[b)]
Anticoagulants	47 (9.3)	19 (7.2)	28 (11.6)	0.088[b)]
Laboratory value				
WBC (×10^3/μL)	8.0 ± 3.0	7.3 ± 2.2	8.8 ± 3.5	<0.001[a)]*
Hemoglobin (g/dL)	12.4 ± 2.3	13.2 ± 2.1	11.6 ± 2.3	<0.001[a)]*
Hematocrit (%)	37.8 ± 6.4	39.8 ± 5.9	35.6 ± 6.3	<0.001[a)]*
Platelet (×10^3/μL)	239.5 ± 90.5	227.9 ± 69.1	252.2 ± 107.8	0.003[a)]*
Total cholesterol (mg/dL)	146.7 ± 43.8	153.8 ± 44.9	136.9 ± 40.4	<0.001[a)]*
TG (mg/dL)	142.0 ± 102.6	158.5 ± 121.0	117.6 ± 59.6	<0.001[a)]*
HDL (mg/dL)	42.8 ± 12.8	45.2 ± 13.1	39.3 ± 11.6	<0.001[a)]*
LDL (mg/dL)	88.2 ± 58.7	94.9 ± 70.4	78.6 ± 34.1	0.013[a)]*
HbA1c (%)	7.5 ± 4.2	7.6 ± 5.7	7.3 ± 1.8	0.501[a)]
ESR (mm/hr)	25.9 ± 23.0	18.6 ± 16.5	35.7 ± 26.8	<0.001[a)]*
hs-CRP (mg/L)	4.3 ± 9.9	2.3 ± 7.3	6.6 ± 11.6	<0.001[a)]*
eGFR (mL/min/1.73 m^2)	68.5 ± 33.5	72.2 ± 26.8	64.4 ± 39.1	0.011[a)]*
Ankle-brachial index	0.7 ± 0.3	0.7 ± 0.3	0.6 ± 0.4	0.021[a)]*
Claudication	391 (77.3)	264 (100)	152 (62.8)	<0.001[b)]*
Claudication distance (m)	181.7 ± 224.0	215.5 ± 231.1	118.1 ± 194.4	<0.001[a)]*
WIQ score	56.4 ± 18.4	57.6 ± 16.4	54.5 ± 21.2	0.166[a)]

Values are presented as number only, mean ± standard deviation, or number (%).
IC, intermittent claudication; CLTI, chronic limb-threatening ischemia; HbA1c, glycated hemoglobin; hs-CRP, high sensitivity CRP; eGFR, estimated glomerular filtration rate; WIQ, Walking Impairment Questionnaire.
[a)]Student t-test, [b)]chi-square test. [c)]eGFR < 60 mL/min/1.73 m^2.
*P < 0.05, statistically significant.

endovascular revascularization. Patients with IC had 405 target vessels in 264 limbs, and patients with CLTI had 420 target vessels in 242 limbs. The most commonly affected vessel was the FP segment (41.8% of cases), followed by the AI segment (31.9%) and BTK arteries (26.3%). Notably, while the frequency of FP segment involvement was similar between 2 groups, the IC group had a higher prevalence of AI segment involvement (63.3% *vs.* 39.7%, P < 0.001), whereas BTK lesions were more frequent in the CLTI group (23.9% *vs.* 63.6%, P < 0.001). Furthermore, multilevel disease was more prevalent in the CLTI group (43.9% *vs.* 57.4%, P = 0.002). According to TASC, the prevalence of *de novo* lesions, defined as the lesions that have not been treated with operation or endovascular treatment, and anatomical grading did not significantly differ between the 2 groups in either the AI or FP segments (Fig. 2 and Table 2).

Endovascular strategies

There were no significant differences in endovascular procedures such as balloon angioplasty (BAP) and stenting in AI lesions (Table 3). Percutaneous atherectomy was more frequently performed in the FP lesions of the IC group (61.1% *vs.* 40.5%, P < 0.001), while the use of BAP and stenting did not significantly differ between the 2 groups (BAP: 84.6% *vs.* 83.5%, P = 0.792; stenting: 29.1% *vs.* 35.3%, P = 0.221) (Table 4). For

Table 2. Distribution of target limb disease in patients with IC and CLTI undergoing endovascular treatment

Variable	IC group (n = 264)	CLTI group (n = 242)	P-value[a)]
AI	167 (63.3)	96 (39.7)	<0.001*
De novo lesion	146 (87.4)	76 (79.2)	0.188
Anatomical grading			0.742
A	30 (18.0)	25 (26.0)	
B	41 (24.6)	43 (44.8)	
C	36 (21.6)	30 (31.3)	
D	28 (16.8)	20 (20.8)	
FP	175 (66.3)	170 (70.2)	0.339
De novo lesion	131 (74.9)	128 (75.3)	0.833
Anatomical grading			0.064
A	24 (16.0)	20 (24.7)	
B	86 (49.1)	66 (38.8)	
C	35 (20.0)	32 (18.8)	
D	28 (16.0)	46 (27.1)	
BTK	63 (23.9)	154 (63.6)	<0.001*
De novo lesion	51 (81.0)	133 (86.4)	0.246
Target artery			0.597
ATA	5 (7.9)	32 (20.8)	
PTA	3 (4.8)	31 (20.1)	
Peroneal artery	3 (4.8)	11 (7.1)	
Pedal artery	0 (0.0)	2 (1.3)	
Single-level disease	148 (56.1)	103 (42.6)	<0.001*
AI	83 (56.1)	25 (24.3)	
FP	59 (39.9)	34 (33.0)	
BTK	6 (4.1)	44 (42.7)	
Multilevel disease	116 (43.9)	139 (57.4)	0.002* <0.001*
Ipsilateral AI + FP	59 (50.9)	29 (20.9)	
Ipsilateral FP + BTK	32 (27.6)	68 (48.9)	
Ipsilateral AI + BTK	0 (0)	3 (2.2)	
Ipsilateral AI + FP + BTK	25 (21.6)	39 (28.1)	

Values are presented as number (%).
IC, intermittent claudication; CLTI, chronic limb-threatening ischemia; ATA, anterior tibial artery; PTA, posterior tibial artery; AI, aortoiliac; FP, femoropopliteal; BTK, below-the-knee.
[a)]Chi-square test.
*P < 0.05, statistically significant.

Table 3. Comparison of endovascular treatment for IC and CLTI: aortoiliac

Variable	IC group (n = 167)	CLTI group (n = 96)	P-value
Balloon angioplasty	141 (84.4)	76 (79.2)	0.279[a)]
Stenting	114 (68.3)	63 (65.6)	0.661[a)]
No. of used stents			0.056[a)]
1	99 (86.8)	47 (74.6)	
2	15 (13.2)	14 (22.2)	
3	0 (0)	1 (1.6)	
4	0 (0)	1 (1.6)	
Stent diameter (mm)	8.3 ± 1.4	8.1 ± 1.1	0.665[b)]
Stent length (mm)	66.5 ± 35.5	57.7 ± 31.9	0.453[b)]

Values are presented as number (%) or mean ± standard deviation.
IC, intermittent claudication; CLTI, chronic limb-threatening ischemia.
[a)]Chi-square test, [b)]Student t-test.

BTK lesions, BAP was more commonly performed in the CLTI group than in the IC group (34.9% *vs.* 74.7%, P < 0.001) (Table 5).

In the case of multilevel diseases, overall, more treatment for multilevel lesions was performed in the CLTI group. In particular, there was a significant difference when FP and BTK lesions were present simultaneously (Supplementary Table 3).

Outcomes after endovascular treatment

Procedural failure

Table 6 shows the procedural outcomes in the IC and CLTI groups. There were no significant differences in procedural failure rates between the 2 groups in all AI, FP, and BTK segments (P = 0.610, P = 0.136, and P = 0.378, respectively).

Follow-up clinical outcomes

At the 1-month follow-up, the IC group showed significantly higher ABI improvement, defined as an increase of ABI more than 0.15, compared to the CLTI group (54.5% *vs.* 27.3%, P < 0.001), whereas WIQ score increased similarly in both groups (52.1% *vs.* 53.4%, P = 0.064). Compared to the IC group, the CLTI patients showed significantly worse rates of primary patency, amputation, and mortality (P = 0.029, P < 0.001, and P < 0.001, respectively) (Fig. 3). There were no significant differences between the 2 groups regarding 6-month cumulative incidences of TLR/TVR (TLR: 2.9% *vs.* 6.5%, P = 0.155; TVR: 6.8% *vs.* 8.2%; P = 0.584). After adjusting confounding factors through multivariable analysis, patients with CLTI had a tendency to higher rates of MALE and loss of primary patency at 6 months, although it was not statistically significant (hazard ratio [HR], 2.13; 95% confidence interval [CI], 0.57–7.93; P = 0.234 and HR, 1.65; 95% CI, 0.96–2.92; P = 0.084). Moreover, the mortality and amputation rates at 6 months were significantly higher in the CLTI group (HR, 8.01; 95% CI, 1.76–36.46; P = 0.007 and HR, 26.86; 95% CI, 3.41–211.52; P = 0.002) (Table 7).

DISCUSSION

PAD is highly prevalent in Asia, particularly among individuals with DM and end-stage renal disease [8-11]. However, there is a notable dearth of data on PAD in Asian patients within the United States, underscoring the importance of collecting data from national registries for ongoing monitoring. While a recent report analyzed the severity and postoperative outcomes of Asian patients with PAD using the Society for Vascular Surgery Vascular Quality Initiative

Table 4. Comparison of endovascular treatment for IC and CLTI: femoropopliteal

Variable	IC group (n = 175)	CLTI group (n = 170)	P-value
Balloon angioplasty	148 (84.6)	142 (83.5)	0.792[a)]
Residual stenosis (%)			0.901[a)]
≤30	69 (87.3)	71 (88.8)	
>30 and ≤50	9 (11.4)	9 (11.3)	
>50%	1 (1.3)	0 (0)	
Stenting	51 (29.1)	60 (35.3)	0.221[a)]
No. of used stents			0.250[a)]
1	25 (49.0)	35 (58.3)	
2	18 (35.3)	17 (28.3)	
3	6 (11.8)	8 (13.3)	
4	2 (3.9)	0 (0)	
Stent diameter (mm)	6.0 ± 0.5	6.0 ± 0.5	0.919[b)]
Stent length (mm)	107.1 ± 37.8	103.9 ± 54.7	0.744[b)]
Percutaneous atherectomy	107 (61.1)	69 (40.6)	<0.001[a)]*
Combined balloon angioplasty	25 (23.4)	15 (21.7)	0.802[a)]

Values are presented as number (%) or mean ± standard deviation.
IC, intermittent claudication; CLTI, chronic limb-threatening ischemia.
[a)]Chi-square test, [b)]Student t-test.
*P < 0.05, statistically significant.

Table 5. Comparison of Endovascular treatment for IC and CLTI: below the knee

Variable	IC group (n = 63)	CLTI group (n = 154)	P-value[a)]
Balloon angioplasty	22 (34.9)	115 (74.7)	<0.001*
Residual stenosis (%)			0.658
≤30	18 (100)	91 (88.3)	
>30 and ≤50	0 (0)	7 (6.8)	
>50	0 (0)	5 (4.9)	

Values are presented as number (%).
IC, intermittent claudication; CLTI, chronic limb-threatening ischemia.
[a)]Chi-square test.
*P < 0.05, statistically significant.

Table 6. Procedural outcomes of endovascular treatment for IC and CLTI

Procedural failure	IC group (n = 258)	CLTI group (n = 237)	P-value[a)]
Aortoiliac	2 (0.8)	2 (0.8)	0.610
Femoropopliteal	2 (0.8)	6 (2.5)	0.136
Below the knee	3 (1.2)	7 (3.0)	0.378

Values are presented as number (%).
IC, intermittent claudication; CLTI, chronic limb-threatening ischemia.
[a)]Chi-square test.

Peripheral Vascular Intervention dataset, it only included patients from Singapore [12]. Given that PAD can be influenced by factors such as race, socioeconomic status, and comorbidities, continuous data collection from national registries is crucial for monitoring, evaluation, and treatment strategies [13-16]. To the best of our knowledge, this study is the first to compare the endovascular approach in Korean patients with PAD who have IC or CLTI, utilizing data collected by the KSVs.

Several established risk factors for PAD include male sex, older age, DM, smoking, hypertension, and hypercholesterolemia [4,7,17]. In our study, the study population had an average age of 71.4 years, with the majority being male (83.3%) and having DM (55.4%) and hypertension (76.1%). However, the percentage of current smokers in our study was only 32.7%, reflecting a decreasing trend in smoking prevalence among Korean adults in recent decades. The general population's current smoker prevalence in 2020 was reported to be 20.6%, while patients with PAD showed a higher prevalence [18]. In our study population, 52.2% presented with IC, while 47.8% presented with CLTI. Previous studies have identified smoking, older age, DM, and CKD as risk factors for CLTI [7,19,20]. In our study, DM and CKD were more prevalent in the CLTI group than in the IC group. Conversely, male sex, hypercholesterolemia, and smoking were less prevalent in the CLTI group than in the other group. Therefore, our findings suggest that DM and CKD are the most significant factors in the development of CLTI, which is consistent with the findings of a previous 2017 domestic study on PAD patients who underwent endovascular treatment [21]. CLTI is a complex, chronic condition that affects both macro- and microvascular systems, leading to reduced blood flow, tissue hypoxia, and edema. Microvascular dysfunction further exacerbates edema formation, leading to impaired diffusion of nutrients to the tissues [19,22]. DM and CKD are known to be

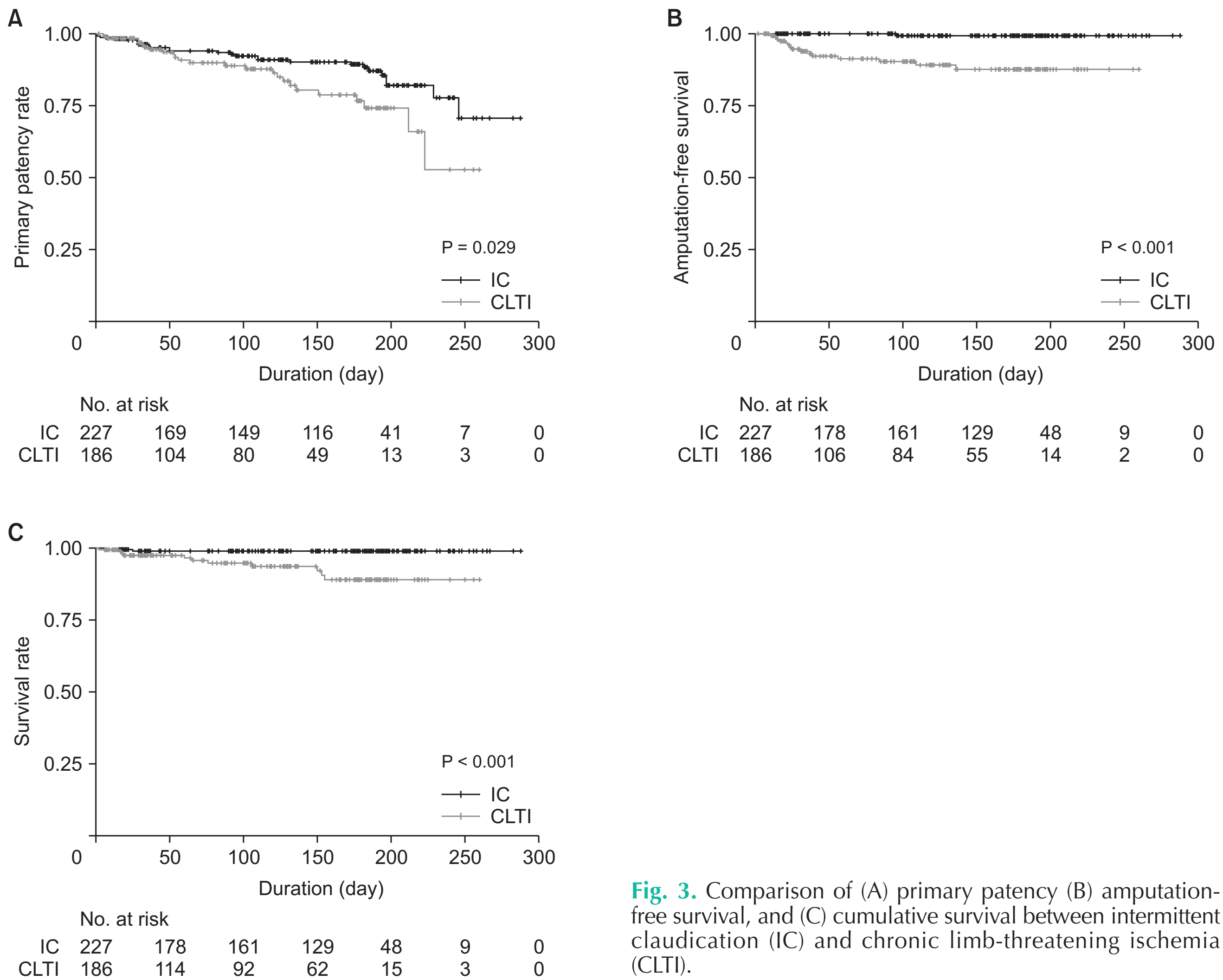

Fig. 3. Comparison of (A) primary patency (B) amputation-free survival, and (C) cumulative survival between intermittent claudication (IC) and chronic limb-threatening ischemia (CLTI).

Table 7. Unadjusted and adjusted 6-months outcomes

Variable	Unadjusted		Adjusted	
	HR (95% CI)	P-value	HR (95% CI)	P-value
Major adverse limb events[a)]	2.13 (0.57–7.93)	0.261	2.35 (0.58–9.55)	0.234
Mortality	8.89 (1.96–40.23)	0.005*	8.01 (1.76–36.46)	0.007*
Amputation	24.28 (3.20–184.07)	0.002*	26.86 (3.41–211.52)	0.002*
Target lesion revascularization	2.34 (0.70–7.78)	0.167	2.09 (0.62–7.08)	0.236
Target vessel revascularization	1.28 (0.53–3.11)	0.585	1.10 (0.44–2.74)	0.838
Loss of primary patency	1.84 (1.06–3.21)	0.031*	1.65 (0.96–2.92)	0.084
Loss of assisted Primary patency	1.86 (0.26–13.26)	0.536	3.34 (0.40–27.70)	0.264
Loss of secondary patency	1.97 (0.94–4.13)	0.071	1.74 (0.81–3.72)	0.154

HR, hazard ratio; CI, confidence interval.
Multivariable analysis adjusting for age, sex, diabetes, chronic kidney disease, and cardiac disease.
[a)]Composite of mortality, amputation, target lesion revascularization, or target vessel revascularization.
*P < 0.05, statistically significant.

associated with elevated levels of systemic inflammation and oxidative stress [23,24]. Our study's laboratory findings, which indicate significant increases in inflammatory markers such as WBC, ESR, and hs-CRP in the CLTI group, align with these known associations.

The rate of FP segment involvement was found to be the highest in our study population receiving endovascular treatment, with no significant difference between the IC and CLTI groups. The involvement of the AI segment was significantly higher in the IC group than in the CLTI group, while the latter showed a significantly higher incidence of BTK segment lesions than the former. These findings align with previous domestic data [21]. Additionally, our study provides, for the first time, insights into the angiographic distribution of multilevel disease in the Korean registry. Multilevel disease was more frequently observed in the CLTI group, with a higher rate of involvement in both the FP and BTK systems than in the other group. Further, the IC group had a higher rate of multilevel disease involving the AI and FP systems than the other group.

Our study also showed differences in real-world endovascular approaches between IC and CLTI. In cases of AI lesions, BAP and stenting were the predominant treatment modalities for both IC and CLTI patients, without significant differences. The AI segment is a critical target for IC treatment, as relieving proximal obstruction frequently results in symptomatic relief. Primary stenting is now considered the first-line endovascular approach for iliac lesions, although this paradigm is mainly based on observational data [25]. In CLTI patients with BTK lesions, BAP was more commonly used as the primary treatment, possibly due to the smaller vessel sizes, where specialized stent technology may not be readily available. Therefore, the utilization of stents was higher in the FP segment than in BTK lesions. Although reports support the use of stents as endovascular strategies for FP PAD, our results showed relatively low rates of stent usage [26,27]. This discrepancy may be attributed to the emergence of drug-coated balloons in recent years. Regarding the use of atherectomy in treating FP PAD lesions, Shammas et al. [28] reported no significant differences in clinically driven TLR when comparing directional atherectomy and angioplasty. The COMPLIANCE 360 trial in 2014 similarly reported negative findings for orbital atherectomy and angioplasty [29]. Despite the lack of compelling data supporting the use of atherectomy for FP PAD lesions, our study found that atherectomy was performed in 61.1% of IC patients with FP lesions, significantly higher than that in the CLTI group. This suggests that atherectomy was more likely attempted in the IC group than the other group, which typically involves more proximal vessels and may exhibit more severe calcification based on the medical provider's judgment than CLTI.

In our study, we found that CLTI patients had significantly higher rates of mortality and amputation at 6 months, as confirmed through adjusted multivariable analysis, aligning with previous research findings [30].

The study had several limitations. It only reported short-term outcomes, and late events within this patient population were not captured. Furthermore, there has been selective bias due to variations in the registration rate at each center, potentially influenced by treatment policies and variations in data entry completeness. It would be necessary to supplement the registry with treatment details so that the data on treatment policies according to lesions can be better established. In addition, it did not incorporate a direct comparison using the comprehensive Health Insurance Review and Assessment Service (HIRA) [17] data from Korea. Considering that this data represents a vast portion of the Korean patient population, this omission could limit the generalizability of our findings. Therefore, future studies making comparisons using HIRA data could enhance our understanding and provide an improved comprehensive perspective, further solidifying the implications of our research.

In conclusion, our study highlights significant differences in baseline and lesion characteristics, endovascular strategies, and short-term follow-up outcomes between patients with IC and CLTI among Korean PAD patients. Our findings could contribute to a better understanding of emerging new endovascular devices and techniques, as well as PAD lesion characteristics in the Korean population, and aid in the establishment of more effective treatment strategies.

SUPPLEMENTARY MATERIALS

Supplementary Tables 1–3 can be found via https://doi.org/10.4174/astr.2024.106.6.344.

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