

# Outcome of Percutaneous Transluminal Angioplasty in Diabetic Patients with Critical Limb Ischaemia

## Authors

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## Key words

- critical limb ischaemia
- peripheral arterial disease
- percutaneous transluminal angioplasty
- diabetes

## Abstract



**Objective:** We investigated the clinical outcome of percutaneous transluminal angioplasty (PTA) which has not been fully established in diabetic patients with critical limb Ischaemia (CLI) compared with non-diabetics.

**Design and patients:** A total of 73 limbs of 52 patients (50 limbs of 34 diabetic patients and 23 limbs of 18 non-diabetics) who underwent PTA for CLI (Rutherford-Becker category 4, 5 or 6) were enrolled. Rates of amputation and restenosis, and ankle brachial index (ABI), were assessed before and after PTA during a 36-month follow-up period.

**Results:** Diabetic patients had a higher rate of major amputations after PTA (10 vs. 0%,  $P < 0.05$ );

however, total amputation (12.0 vs. 8.7%,  $P = 0.62$ ) and restenosis rates (4.0 vs. 8.7%,  $P = 0.38$ ) were not significantly different compared with non-diabetic patients. ABI at 3 months after PTA was significantly improved in both diabetic and non-diabetic patients ( $0.70 \pm 0.20$  vs.  $0.93 \pm 0.19$ ,  $P < 0.01$  in diabetic patients;  $0.69 \pm 0.25$  vs.  $0.92 \pm 0.17$ ,  $P < 0.01$  in non-diabetics). Improved ABI was maintained for 36 months in both groups and did not show a significant difference ( $0.88 \pm 0.21$  vs.  $0.89 \pm 0.20$ ,  $P = 0.89$ ).

**Conclusion:** Our results, showing that the outcome of PTA in diabetic patients is not inferior to that in non-diabetics, suggest the potential benefit of primary PTA, instead of bypass surgery, for CLI in diabetic patients who are at high risk of perioperative complications.

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## Introduction



Critical limb ischaemia (CLI) is a manifestation of peripheral artery disease (PAD) with chronic ischemic rest pain and skin lesions (ulcers or gangrene) [1]. In most developed countries, the incidence of critical limb Ischaemia is estimated to be 50–100 per 100 000 individuals per year. CLI causes pronounced morbidity and mortality, as well as the consumption of many health-care resources [1]. Of patients with PAD, 1–3% experience CLI, and among those who develop CLI, 30% have an amputation and 25% die within 1 year [1]. Revascularisation and adequate tissue oxygenation are essential factors in CLI management [2]. Options for revascularisation include bypass graft surgery, percutaneous transluminal angioplasty (PTA), and a combination of both surgery and endovascular therapy. Bypass graft surgery has been the mainstay of revascularisation therapy. However, bypass surgery is an invasive procedure associated with high perioperative

morbidity and mortality, especially in diabetic patients with numerous vascular comorbidities resulting from systemic atherosclerosis [3,4]. In the past decade, bypass surgery has been largely replaced by PTA, whose advantages are low procedural morbidity and mortality, reduced costs and shorter hospital stays [5–9]. Furthermore, PTA can be repeated in cases of technical failure or restenosis. Moreover, it preserves collaterals so that even if the angioplasty site occludes, symptoms may not return and the healed status of lost tissue may be maintained [9].

PAD is almost 3 times more frequent [10] and CLI due to PAD has poorer outcomes with respect to amputation and mortality in diabetic patients compared with non-diabetics [11]. Arterial lesions are more diffuse, tend to involve distal arteries, and are frequently bilateral in diabetic patients [11,12]. Although PTA is an alternative to bypass surgery for CLI, there are concerns about its feasibility and long-term results in diabetic patients, particularly in the treatment of below-the-knee lesions.

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A significantly better outcome is now expected for CLI in diabetic patients, based on the improved technical options and expanded indications of PTA [13]. However, there have been few studies regarding the outcomes of PTA in diabetic patients with CLI, especially for below-the-knee lesions. In this study, we compared the clinical outcomes of PTA for CLI in diabetic patients and non-diabetics, focusing on below-the-knee lesions.

## Materials and Methods

### Study subjects

We retrospectively recruited 59 patients with CLI at Konkuk University Hospital, Seoul, Korea, between August 2005 and February 2009. The severity of vascular stenosis was evaluated by ankle brachial index (ABI) and CT angiography, and eligibility criteria were as follows: (1) CLI (Rutherford-Becker category 4, 5 or 6) [14], (2) ABI of the affected limb of  $\leq 0.9$  and (3) presence of a critical lesion (stenosis of diameter  $> 75\%$ ) in the infra-inguinal artery, as determined by CT angiography. We excluded patients who had previously undergone interventions for CLI and those with clinical or imaging evidence of embolic disease. Ultimately, we enrolled 52 patients, of whom 34 (65.4%) were diabetics and 18 (34.6%) were non-diabetics (see Fig. 1). Eligible patients ( $n=52$ ) underwent PTA within 1 week of their diagnosis of CLI, and underwent follow-up assessments at months 3, 12, 24 and 36. Long-term aspirin (100mg, once daily) was administered indefinitely and clopidogrel (75 mg, once daily) was co-administered for 4 weeks after PTA. The protocol was reviewed and approved by the institutional review board of Konkuk University Hospital (No. KUH 1010396) and was performed in accordance with the Declaration of Helsinki.

### Assessment of atherosclerosis risk factors

Height and body weight were measured to the nearest 0.1 cm and 0.1 kg, respectively. Body mass index (BMI) (in  $\text{kg}/\text{m}^2$ ) was calculated as weight divided by height squared. Waist circumference was measured at the narrowest point between the lower limit of the ribcage and the iliac crest. Blood pressure was recorded 2 times after the subjects had been in a relaxed state for at least 10 min. There was a 5-min rest period between measurements.

After an overnight (14-h) fast, venous blood samples were drawn from the antecubital vein and plasma was separated by centrifugation (2000 rpm, 20 min,  $4^\circ\text{C}$ ) for biochemical measurements. The fasting plasma glucose, total cholesterol, triglyceride, high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol levels were measured using a Toshiba 200FR Autoanalyser (Toshiba Medical Systems Co., Ltd, Tokyo, Japan) and A1c levels were measured using a VARIANT II TURBO 2.0 kit (Bio-Rad Laboratories, Hercules, CA, USA). History of smoking, diabetes, hypertension, dyslipidaemia, stroke, and coronary artery disease was recorded in a standardised way.

### Measurement of ankle brachial index

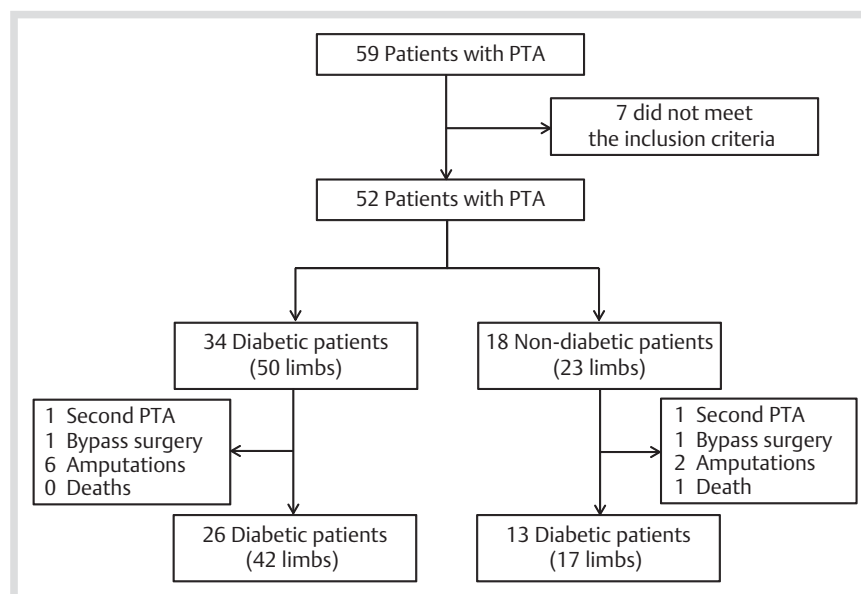
ABI was measured using a 5-mHz Doppler probe before and 3, 12, 24 and 36 months after PTA using a VaSera Vs-1000 screening system (Fukuda Denshi, Japan). Systolic blood pressure was recorded in the upper extremities in the brachial arteries and in the lower extremities in the posterior tibial arteries with each subject in the supine position after 10 min of rest. The ABI for each leg was separately calculated by dividing the higher of the 2 ankle pressures by the brachial artery pressure.

### PTA Procedure

All procedures were performed under local anaesthesia by an interventional radiologist with fluoroscopy guidance. At the beginning of the PTA procedure, 5000 IU of heparin was injected into the artery. Vascular access for intervention was achieved via the common femoral artery. A 6-F guiding sheath (Terumo Kabushiki Kaisha, Tokyo, Japan) was positioned to perform PTA, and a 0.035-inch guide wire (Terumo Kabushiki Kaisha, Tokyo, Japan) was inserted to pass through the arterial obstruction, followed by a 3.0–5.0 mm balloon catheter (Savvy, Cordis Endovascular, Miami, FL, USA).

### Statistical analysis

All continuous variables with normal distributions are expressed as the mean  $\pm$  SD; categorical data are expressed as percentages. The Mann-Whitney U-test and Fisher's exact test were used to compare variables between diabetic and non-diabetic patients. Differences in the distribution of vascular stenoses requiring PTA between groups were analysed by  $\chi^2$  test. Paired Student's *t*-tests



**Fig. 1** Enrolment and follow-up of the study patients.

**Table 1** Baseline characteristics of the patients with critical limb ischemia.

	DM N=34	Non-DM N=18	P
age (years)	68.4±10.5	71.6±7.0	0.25
male (%)	26 (76.5)	15 (83.3)	0.43
duration of DM (years)	16.1±9.4	–	–
body mass index (kg/m <sup>2</sup> )	24.5±3.7	23.5±3.9	0.67
smoking (%)	23 (67.6)	16 (88.9)	0.04
current	16 (47.1)	13 (72.2)	0.02
past	7 (20.6)	3 (16.7)	0.67
hypertension (%)	27 (79.4)	15 (83.3)	0.57
dyslipidemia (%)	28 (82.4)	14 (77.8)	0.02
coronary artery disease (%)	15 (44.1)	8 (44.4)	0.12
cerebrovascular disease (%)	8 (23.5)	3 (16.7)	0.35
fasting plasma glucose (mmol/l)	9.2±3.0	6.9±1.1	0.03
A1c (%)	8.1±1.7	5.6±0.8	0.01
total cholesterol (mmol/l)	4.8±1.0	4.6±0.9	0.58
triglycerides (mmol/l)	2.0±1.4	1.9±1.4	0.69
HDL-cholesterol (mmol/l)	1.3±0.3	1.4±0.4	0.75
LDL-cholesterol (mmol/l)	2.8±0.8	3.0±0.9	0.46
creatinine (μmol/l)	76.4±16.4	68.6±14.3	0.35
ankle brachial index	0.70±0.20	0.69±0.25	0.18
clinical category [14]			
Rutherford-Becker 4	12 (35.3)	7 (38.9)	0.67
Rutherford-Becker 5 or 6	22 (64.7)	11 (61.1)	0.78

Data are means ± SD

**Table 2** Numbers and locations of lesions that needed PTA in diabetic and non-diabetic patients.

	DM N=34	Non-DM N=18	P
number of limbs affected	50	23	
total number of lesions	88	45	
lesions/patient	2.5±1.6	2.5±1.0	0.89
lesions/affected limb	1.8±1.5	2.0±1.2	0.67
patients with ≥5 lesions	3 (8.8%)	0 (0%)	0.00
3–4 lesions	13 (38.2%)	10 (55.6%)	0.08
1–2 lesions	18 (53.0%)	8 (44.4%)	0.12
number of lesions involved			
supra-popliteal	43 (48.9%)	27 (60.0%)	0.10
popliteal	15 (17.0%)	8 (17.8%)	0.86
infra-popliteal	30 (34.1%)	10 (22.2%)	0.03

Data are means ± SD

were used to evaluate the change in ABI in each group. To evaluate the factors associated with the detrimental outcome, we used logistic regression analysis. The detrimental outcome was defined as amputations of limb or restenosis. A *P*-value of <0.05 was considered statistically significant. All analyses were performed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA).

## Results

### Baseline characteristics (Table 1)

Among 52 eligible patients with CLI, 34 (65.4%) were diabetics and 18 (34.6%) were non-diabetics. Of the diabetic patients (DM group), 76.5% were male (*n*=26) and the mean age was 68.4±10.5 years. The duration of diabetes was 16.1±9.4 years and mean A1c was 8.1±1.7%. Of the non-diabetic patients (non-DM group), 83.3% were male (*n*=15) and the mean age was 71.6±7.0 years. There were no differences between the 2 groups

in the prevalence of smoking, hypertension, coronary artery disease and stroke. The prevalence of dyslipidaemia was significantly higher in the DM group (85.0 vs. 55.0%, *P*=0.01) and the proportion of current smokers was higher in the non-DM group (72.2 vs. 47.1%, *P*=0.01). There was no difference in baseline ABI of the affected limb (0.70±0.20 vs. 0.69±0.25, *P*=0.18) or Rutherford-Becker category between the groups. For below-the-knee lesions (DM group, 39 limbs; non-DM group, 16 limbs), the ABI of the affected limbs was also similar in the 2 groups (0.62±0.30 vs. 0.65±0.28, *P*=0.33). Other baseline characteristics of patients with below-the-knee lesions were similar in the DM and non-DM groups (data not shown).

### Number and location of arterial lesions requiring PTA

The numbers and locations of arterial lesions which required PTA in the DM and non-DM groups are shown in Table 2. PTA procedures were carried out in 50 limbs and a total of 88 arterial lesions in the DM group, and in 23 limbs and a total of 45 lesions in the non-DM group. The number of lesions requiring PTA per patient was not significantly different between the DM and non-DM groups; however, the proportions of patients with more than five lesions (8.8 vs. 0%, *P*<0.05) and with infra-popliteal lesions (34.1 vs. 22.2%, *P*<0.05) were higher in the DM group.

### Outcome of PTA

#### Amputation and restenosis

During 36 months of follow-up after PTA, 6 (12.0%) of 50 affected limbs of diabetic patients (DM group) required amputation. Of these amputations, 5 (10.0%) were major amputations and one (2.0%) was a minor amputation (Table 3). 4 major amputations were required within 30 days, and one major and one minor amputation were performed at 2 and 3 years after PTA, respectively. Restenosis occurred in 2 limbs of diabetic patients (4.0%); one limb (2.0%) was subjected to PTA for a second time and the other (2.0%) was treated with bypass surgery. Among 23 affected limbs in the non-DM group, 2 (8.7%) required minor amputations within 30 days of PTA and restenosis occurred in 2 limbs (8.7%) during follow-up. Although the prevalence of major amputations was higher in the DM group compared with the non-DM group, all of the patients who underwent major amputations were initially Rutherford-Becker category 6. The rates of major plus minor amputations, minor amputations and restenosis after PTA were not significantly different between the 2 groups. All patients who underwent amputations and secondary PTA or bypass surgery had below-the-knee lesions. One patient in the non-DM group died due to oesophageal cancer during follow-up. Logistic regression analysis was performed to identify the predictive factors for the detrimental outcome. The adjusted odds ratio for the detrimental outcome was 1.6 [95% CI: 1.3–2.5, *P*=0.03] and 2.1 [95% CI: 1.4–3–3.1, *P*=0.01] if the subjects had hyperglycaemia (HbA1c >8.0%) or belonged to high grade Rutherford-Becker scores (5 or 6). The presence of hypertension, dyslipidaemia or smoking status was not significantly associated with the outcome; 1.3 [95% CI: 0.8–2.1, *P*=0.73], 1.2 [95% CI: 0.7–2.0, *P*=0.68] and 1.5 [95% CI: 0.9–2.3, *P*=0.53], respectively.

#### Serial changes in ABI after PTA

Changes in ABI during the 36 months after PTA are shown in Fig. 2a. ABI at 3 months after PTA was significantly improved compared with ABI before PTA in both the DM and non-DM groups (0.70±0.20 vs. 0.93±0.19, *P*<0.01 in the DM group;

0.69±0.25 vs. 0.92±0.17,  $P<0.01$  in the non-DM group), and was not significantly different between the 2 groups (0.93±0.19 vs. 0.92±0.17,  $P=0.89$ ). Improved ABI was maintained for 36 months in patients in the DM group ( $n=26$ ) and the non-DM group ( $n=13$ ) group (patients who underwent amputation or revascularisation for restenosis, or who died during 36 months after PTA were excluded from the analysis). ABI was similar in the DM and non-DM groups at 36 months (0.88±0.21 vs. 0.89±0.20,  $P=0.89$ ) (Table 3). For below-the-knee lesions, changes in ABI in the affected limbs after PTA showed a similar pattern (Fig. 2b). ABI at 3 months after PTA was dramatically improved in both the DM and non-DM groups (0.62±0.30 vs. 0.91±0.12,  $P<0.01$  in the DM group; 0.65±0.28 vs. 0.90±0.18,  $P<0.01$  in the non-DM group) and was not significantly different between the 2 groups. Improved ABI declined slightly with increasing time to follow-up; however, there was no difference between the DM and non-DM groups and it was maintained above 0.8 without recurrence of CLI.

## Discussion

In this study, we demonstrated that successful PTA, comparable with that in non-diabetics, is possible for CLI in diabetic patients, especially in patients with infra-popliteal stenosis. During 36 months of follow-up, ABI of the affected limb that underwent PTA was significantly improved immediately thereafter, and was maintained at an improved level for 36 months in both of DM and non-DM group. The diabetic patients who underwent infra-popliteal PTA also showed significant improvements in ABI in affected limbs (comparable with the non-DM group) during 36 months of follow-up. Although the rate of major amputations within a month of PTA was high, the rates of major plus minor amputations and restenosis were not significantly different between the DM and non-DM group.

The prevalence of hypertension, dyslipidaemia, and other macrovascular complications including coronary artery disease and cerebrovascular disease was high in the diabetic patients enrolled in our study compared with the Korean population of patients with type 2 diabetes [15]. As we studied patients with PAD, these results indirectly indicate a high prevalence of atherosclerotic risk factors and complications in patients with PAD. These results support those of a recent report, which recommended routine ABI for patients with coronary artery disease and cerebrovascular disease, who also have high prevalence of PAD [16].

We found that there was no significant difference in the BMI or LDL-cholesterol levels between DM and non-DM groups. On the other hand, the proportion of subjects who smoke was significantly higher in non-DM group. We postulate that the higher smoking rate in the non-DM group should have contributed to the comparable ABI values between 2 groups since smoking is a well-established risk factor for atherosclerotic vascular diseases. It should be noted that although the baseline ABI was similar between DM and non-DM groups and the proportion of smokers was higher in the non-DM groups the diabetic limbs required more major amputations within 30 days. This result indicates the critical role of diabetic state per se in limb-threatening and underscores the importance of tight glycemic control in diabetic patients.

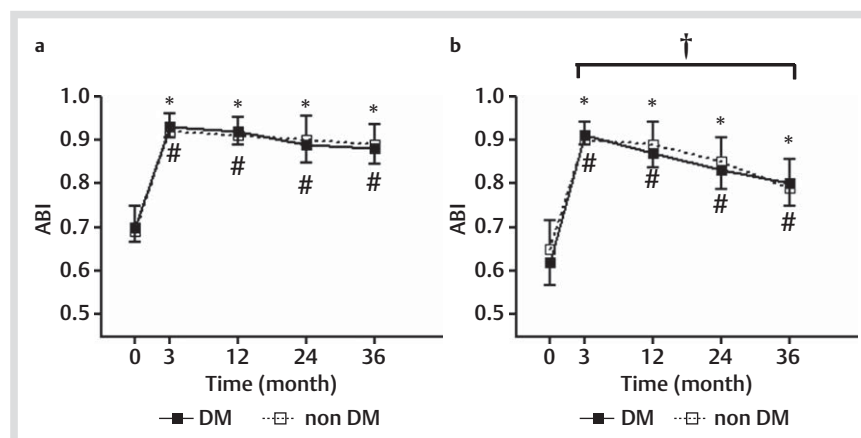
In diabetic patients with CLI, collateral distribution is typically poor because of depression of arteriogenic and collateral growth processes in response to ischaemia. Therefore, similar grades of arterial disease in diabetic patients can lead to more severe ischaemia and necrosis in lower limbs compared with non-diabetics. Furthermore, atherosclerosis in the medial layers of the arterial wall is characterised by concentric continuous calcification in diabetic patients and intimal, eccentric and patchy calcific deposits in non-diabetics [17]. Therefore, more aggressive revascularisation is generally needed, and the technical difficulties associated with revascularisation and poor prognosis have been the major problems with CLI in diabetic patients. Diabetic patients are at high risk of perioperative complications caused by numerous vascular comorbidities. Our results showing that the outcome of PTA in diabetic patients is not inferior to that in non-diabetics suggests potential benefits of primary PTA instead of bypass surgery for CLI in diabetic patients.

**Table 3** Outcome of PTA in CLI of diabetic and non-diabetic patients.

	DM 50 limbs	Non-DM 23 limbs	<i>P</i>
total number of amputations	6 (12.0%)	2 (8.7%)	0.62
major amputations	5 (10.0%)	0 (0%)	0.04
minor amputation	1 (2.0%)	2 (8.7%)	0.25
restenosis	2 (4.0%)	2 (8.7%)	0.38
second PTA	1 (2.0%)	1 (4.3%)	0.48
bypass surgery	1 (2.0%)	1 (4.3%)	0.48
death	0 (0%)	1 (4.3%)*	0.78
ankle brachial index†	0.88±0.21	0.89±0.20	0.89

\* Due to oesophageal cancer

† Patients who underwent amputation or revascularisation for restenosis, or died within 36 months after PTA, were excluded, leaving 26 patients in the DM group and 13 in the non-DM group



**Fig. 2** Changes in ABI of **a** all affected limbs and **b** affected limbs with below-the-knee lesions after PTA in diabetic and non-diabetic patients. \*;  $P<0.01$  vs. before PTA in diabetic patients, #;  $P<0.01$  vs. before PTA in non-diabetic patients, †;  $P<0.01$ .



Several studies have reported the effectiveness of primary PTA for CLI in diabetic patients. Faglia and colleagues reported the results of PTA as the primary choice of revascularisation procedure in 993 diabetic patients with CLI. The rate of major amputations was 1.7% and the rate of restenosis 8.8% during a mean of 26±15 months of follow-up, and 5-year primary patency was 88% [18]. However, this previous study described only the outcomes of PTA in diabetic patients. Lazaris and colleagues showed similar clinical outcomes of subintimal angioplasty in diabetic patients compared to non-diabetics in a retrospective study [19]. This is to our knowledge the first report of favourable outcomes of primary PTA for CLI in diabetic patients, compared with non-diabetics, using ABI.

It is known that PAD lesions are more diffuse, frequently bilateral, and tend to involve distal arteries in diabetic patients [12]. Graziani and colleagues reported vascular involvement in diabetic patients with CLI [20]. Among 2 893 stenotic lesions, 74% were in below-the-knee arteries. Furthermore, 28% of diabetic patients had below-the-knee lesions. In our study, the total number of stenotic lesions per patient or limb was not significantly different between diabetic and non-diabetic patients. However, the proportion of diabetic patients with more than 5 lesions or with below-the-knee stenosis was significantly higher than that of non-diabetic patients regardless of similar baseline ABI.

Our study has several strengths. It is the first to compare directly the outcome of PTA between diabetic patients and non-diabetics with CLI, particularly for infra-cases of popliteal lesions. Furthermore, we evaluated the outcome of PTA by assessing serial changes in ABI for 3 years after PTA (which is considered an objective measure of lower extremity arterial patency), as well as other clinical outcomes, such as amputation and restenosis rates. To date, few studies have evaluated the outcome of PTA by assessing serial changes in ABI.

Our study also has limitations. First, the number of patients enrolled was small. Second, the 36-month follow-up period may not have been long enough to compare the long-term results of PTA in diabetic patients and non-diabetics. Third, ABI is considered an objective measure of arterial patency, with 90% sensitivity and 98% specificity [21, 22]; however, it is a less accurate tool for diabetic patients with below-the-knee medial calcification. In conclusion, the outcome of PTA for CLI in diabetic patients, who are more likely to have multiple lesions and infra-popliteal lesions, is not significantly inferior compared to that in non-diabetics. Our results suggest that PTA is a useful and safe first-line treatment option for CLI in diabetic patients, who have a high risk of perioperative complications caused by vascular comorbidities.

**Conflict of interest:** The authors have no conflicts of interest to declare.

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