Original Article

Transcutaneous Oxygen Tension and Ankle-Brachial Index for Predicting Limb Salvage Outcomes in Patients Treated with Drug-Eluting Stent for Below-the-Knee Critical Limb Ischemia

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Background: Critical limb ischemia [CLI] is a serious cardiovascular condition that causes high morbidity and mortality. CLI can be identified by ankle pressure of less than 50 mmHg, toe pressure of less than 30 mmHg, or transcutaneous oxygen tension [$TcPO_2$] of less than 30 mmHg.

Objective: To investigate the efficacy of $TcPO_2$ and ankle-brachial index [ABI] as predictors of limb salvage outcomes in patients treated with drug-eluting stent [DES] for below-the-knee CLI.

Materials and Methods: This retrospective study was conducted in patients treated for CLI with below-the-knee [BTK] percutaneous transluminal angioplasty [PTA] with DES placement between January 2007 and June 2015 study period. The primary endpoints were pre- and post-procedural ABI and $TcPO_2$. The secondary endpoints were limb salvage rate, time-to-major amputation, and ulcer healing.

Results: Seventy-two patients (79 limbs) were included. Of those, 40 were men and 39 were women, and the mean age was 73.8±8.0 years. The median follow-up time was 349 days and the 1-year limb salvage rate was 95%. Complete wound healing at one year was observed in 76% of patients. Overall ABI was significantly improved from 0.70±0.17 to 0.89±0.26 ($p<0.001$). In isolated below-the-knee DES patients, ABI was significantly improved from 0.74±0.18 to 0.99±0.25 ($p = 0.019$), and $TcPO_2$ was significantly improved from 17.50±9.62 to 35.50±11.84 mmHg ($p = 0.035$).

Conclusion: Long-term outcome of DES placement at BTK level was associated with high limb salvage rate and wound healing, as evidenced by increased ABI and $TcPO_2$.

Keywords: Below-the-knee critical limb ischemia, Drug-eluting stent, Transcutaneous oxygen tension, Wound healing

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Critical limb ischemia [CLI] is a serious cardiovascular condition that causes high morbidity and mortality. Each year, approximately 500 to 1,000 new cases of CLI are reported per 1 million people. Left untreated, CLI can lead to major amputation in 30% of people within 12 months. The 1-year and 2-year mortality rates of CLI are 25% and 32%, respectively[1-3]. According to Inter-Society Consensus for the Management of Peripheral Arterial Disease [TASC II] guidelines, CLI is defined as chronic ischemic rest pain, ulcers, or gangrene that is attributable to arterial occlusive disease. This condition can be identified by one or more of the following: ankle pressure of less than 50 mmHg, toe pressure of less than 30 mmHg, or transcutaneous oxygen tension [$TcPO_2$] of less than 30 mmHg[3].

In the past, the main surgical treatment for CLI was either bypass surgery or primary amputation. However, most CLI patients have multiple co-morbidities, such as diabetes mellitus [DM], hypertension, and/or

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atherosclerotic heart disease, any or all of which are associated with very high perioperative risk. Moreover, a lack of suitable vessels for bypass conduits and inadequate sites for distal anastomosis limit the role of bypass surgery in some patients. Based on the challenges and limitations in this patient population, a new technique was developed to treat CLI. After successful revascularization of the coronary artery, an advanced endovascular technique known as percutaneous transluminal angioplasty [PTA] has been used to treat patients with CLI over the past decade. Previous studies showed similar outcomes relative to amputation-free survival and health-related quality of life between bypass surgery and PTA[4,5]. Furthermore, PTA was found to have a lower perioperative mortality rate and shorter hospital length of stay[4,6]. Thus, endovascular therapy became a promising new treatment in patients with CLI.

Use of a bare metal stent [BMS] was shown to improve 1-year limb salvage rate by more than 90% in patients with CLI[7]. However, the rate of restenosis was still found to be unsatisfactory, ranging from 20% to 60% in infrapopliteal vessels[8-11]. After the discovery that use of a drug-eluting stent [DES] was associated with a lower rate of restenosis in atherosclerotic heart disease, DES essentially replaced BMS for treatment of CLI. In 2009, a meta-analysis study demonstrated the superiority of DES in terms of restenosis and primary patency rate when compared with BMS at BTK level[9].

One of the primary objectives of treatment in CLI is ulcer healing. Diabetic patients may have poorly compressible arteries due to medial calcification of blood vessels. As such, the measurement of ankle-brachial index [ABI] may not be reliable. However, $TcPO_2$ measurement is a non-invasive method that can measure local blood flow and tissue oxygenation around the ulcer. $TcPO_2$ was found to be superior to ankle and toe pressure measurements in diabetic patients relative to prediction of limb salvage and ulcer healing[12,13]. The cut-off value for determination of ulcer healing varied between studies[13,14]. As evidenced by a recent study, a $TcPO_2$ value of 40 mmHg or more is suggestive of a healing ulcer. In contrast, a $TcPO_2$ value of 20 mmHg or less suggests poor ulcer healing outcome and a need for revascularization[15].

$TcPO_2$ measurement was recently used to predict limb salvage rate after BTK angioplasty[12,16]. However, $TcPO_2$ measurement has never been used to predict limb salvage after below-the-knee DES placement. Accordingly, the aim of the present study was to investigate the efficacy of $TcPO_2$ and ABI as predictors of limb salvage outcomes in patients treated with DES for below-the-knee CLI.

Materials and Methods

This retrospective study was conducted in patients who were diagnosed with and treated for CLI at Siriraj Hospital, Bangkok, Thailand. Patients with CLI (Rutherford classification 4-6) who underwent below-the-knee PTA with DES placement between January 2007 and June 2015 were included. All included CLI patients presented with ischemic rest pain, non-healing ulcers, or gangrene of the lower extremities. Ischemic tissue loss was defined according to TASC II guideline, with tissue loss being associated with ankle pressure of less than 70 mmHg or toe pressure of less than 50 mmHg. Most patients were referred from a vascular surgeon as poor surgical candidates with multiple co-morbidities and lack of suitable anatomic vessels. Patients with acute arterial occlusion, contrast media allergy, or anti-platelet or heparin intolerance were excluded. The protocol for the present study was approved by the Siriraj Institutional Review Board [SIRB], Faculty of Medicine Siriraj Hospital, Mahidol University.

ABI was measured before and after PTA procedure in most patients; however, $TcPO_2$ was only measured in patients who had ulcers or gangrene for purposes of predicting ulcer healing.

All patients underwent PTA with placement of at least one DES at BTK level. Vascular access in most patients was made using antegrade approach, either by crossover technique from the contralateral common femoral artery [CFA] or by direct puncture via the ipsilateral CFA. Heparin 5,000 IU was given intra-arterially after vascular access was achieved. Additional heparin was given to maintain an activated clotting time [ACT] of approximately 250 seconds. Multipurpose or right Judkins catheter was used in all procedures. A BMW Hi-Torque Guide Wire 0.014" (Abbott Vascular, Santa Clara, CA, USA) was used to cross the stenosis lesion. In cases with total occlusion, a dedicated 0.014" wire, such as a Fielder XT Guide Wire, Gaia Guide Wire, Miracle Guide Wire, or Confianza Guide Wire (all Asahi Intecc Co., Ltd., Aichi, Japan) used to cross the occluded lesion together with a fine cross catheter. In patients with total occlusion of the infrapopiteal artery in whom antegrade technique failed to cross the occlusion, a retrograde approach technique with access via the pedal artery, such as dorsalis pedis, distal part of posterior tibia, or distal part of peroneal artery, was performed.

An Amphirion Deep 2x80 mm Balloon (Medtronic, Minneapolis, MN, USA) was used to predilate for one minute. DES was then deployed to re-establish flow to distal runoff to the foot. Procedural success was defined as restoration of antegrade perfusion with less than 30% residual stenosis. $TcPO_2$ measurement was performed using a TCM400 Multi-Channel $TcPO_2$ Monitor (Radiometer Medical ApS, Brønshøj, Denmark) at the vascular surgery clinic of each of the 2 study hospitals. A standard barometric pressure of 730 mmHg was used to calibrate the machine for the geographic location (Bangkok, Thailand). A standard electrode was applied to the chest wall and another electrode was applied around the ulcer site. The electrodes were heated to 45°C to enhance local perfusion and open skin pores. The baseline $TcPO_2$ was recorded for at least 20 minutes with the patient laying in the supine position. The baseline $TcPO_2$ measurement was then compared to the $TcPO_2$ measurement taken four weeks after BTK endovascular treatment.

The primary endpoints of the present study were pre- and post-procedural ABI and $TcPO_2$, and ulcer healing. Patients were followed at their respective outpatient cardiology and vascular surgery clinics at 1 to 2, 6, and 12 months post-procedure, with focused attention given to claudicating pain, ulcer healing, peripheral pulse volume, and change in ABI. Repeat measurement of $TcPO_2$ was only performed in patients who had ulcers. Patients who experienced recurrent ischemic claudication or diminished peripheral pulse were re-evaluated with Doppler ultrasound and angiography, accordingly. Data, including ulcer healing, major amputation, and mortality rate were collected, recorded, and analyzed.

Statistical analysis

Categorical data are presented as frequency and percentage, and continuous data are reported as mean ± standard deviation [SD] for normally distributed data and as median (minimum, maximum) for non-normally distributed data. Differences between pre- and post-procedural ABI and $TcPO_2$ were analyzed using paired t-test. MACE free survival is presented using the Kaplan-Meier survival curve. A *p*-value of less than 0.05 was considered to be statistically significant. Statistical analysis was performed using SPSS Statistics version 18.0 (SPSS Inc., Chicago, IL, USA).

Results

Seventy-two patients (79 limbs) were enrolled in the present study. Forty (50.6%) and thirty-nine (49.4%) patients were male and female, respectively. The mean age of subjects was 73.8±8.0 years. Most patients had comorbidities, including DM type 2, hypertension, hypercholesterolemia, and/or coronary arterial disease. The main clinical presentations were ischemic rest pain, non-healing ulcer and gangrene of the lower extremities. Patient demographic and clinical characteristics are summarized in Table 1. DES were deployed in all patients, with a median of two stents per patient and a mean stent length of 52 millimeters. About half of subjects had concomitant superficial femoral artery [SFA] or iliac diseases, and the remaining proportion of patients had isolated BTK diseases. BTK lesion distributions are shown in Table 2. Technical success, defined as less than 30% residual stenosis, was achieved in all patients. The DES used in the present study were coated with sirolimus, paclitaxel, biolimus, zatarolimus, or everolimus. Procedural and vessel characteristics are presented in Table 2.

Table 1. Demographic data of 72 patients

Demographic data	Number (%)
Diabetes mellitus	68 (86.1)
Hypertension	74 (93.7)
Hypercholesterolemia	61 (77.2)
Coronary arterial disease	53 (67.1)
Current smoker	13 (16.5)
Rutherford (n = 79)	
Rutherford category 4	16 (20.0)
Rutherford category 5	36 (46.0)
Rutherford category 6	27 (34.0)

The overall pre-procedural ABI was 0.70±0.17, which was significantly improved to 0.89±0.26 after PTA ($p<0.001$). In subgroup analysis of patients with isolated BTK endovascularization, ABI was significantly increased from 0.74±0.18 before PTA to 0.99±0.25 after PTA ($p = 0.019$). In patients with lower extremity ulcers, the pre-procedural baseline $TcPO_2$ was 17.50±9.62 mmHg, which significantly increased to 35.50±11.84 mmHg after PTA ($p = 0.035$). Clinical outcomes are presented in Table 3.

Immediate complications were observed in three patients (3.8%), with infected thrombosed pseudoaneurysm, vessel perforation, and dissecting vessels occurring in one patient each. The infected thrombosed pseudoaneurysm was successfully treated with surgical drainage and delayed primary wound closure. The minute perforation at the distal anterior tibial artery was resolved with conservative treatment. The dissecting vessels were successfully treated with balloon tamponade and DES placement. No procedure-

Table 2. Procedural and vessel characteristics in 79 CLI limbs

Procedural and vessel characteristics	Number (%)
Treated lesions	
Type of lesion (n = 79)	
• Stenosis	40 (50.6)
• Occluded	39 (49.4)
Disease (n = 83)	
Iliac disease	4 (4.8)
Superficial Femoral artery disease	39 (47.0)
Isolated below-knee disease	40 (48.2)
Arteries treated at below-knee level (n = 125)	
Popliteal artery	13 (10.4)
Tibioperoneal trunk artery	14 (11.2)
Anterior tibial artery	48 (38.4)
Posterior tibial artery	22 (17.6)
Peroneal artery	28 (22.4)
Drug-eluting stents (n = 150)	
Type of DES	
• Sirolimus	80 (53.3)
• Paclitaxel	5 (3.3)
• Biolimus	46 (30.7)
• Zatarolimus	4 (2.7)
• Everolimus	15 (10.0)
Number of stent vessel, mean ± SD	1.32±0.52
Number of DES per patient, median (min-max)	2 (1 to 7)
Diameter of DES (mm), mean ± SD	2.83±0.32
Length of DES (mm), median (min-max)	52 (13 to 235)

CLI = critical limb ischemia; DES = drug-eluting stent; SD = standard deviation

Table 3. Clinical outcomes in 79 CLI limbs

Clinical outcomes	Above- and below-knee interventions (n = 39)	Isolated below-knee interventions (n = 40)
Pre ABI, mean ± SD	0.65±0.17	0.74±0.18
Post ABI, mean ± SD	0.81±0.24	0.99±0.25
p-value	0.009*	0.019*
Pre $TcPO_2$, mean ± SD	26.55±18.02	17.50±9.62
Post $TcPO_2$, mean ± SD	40.36±15.40	35.50±11.84
p-value	0.027*	0.035*
Immediate complications, n (%)	2 (5.1)	1 (2.5)
Follow-up (n = 56), n (%)	(n = 31)	(n = 25)
Limb salvage	29 (94.0)	24 (96.0)
Major amputations	2 (6.5)	1 (4.0)
rePTA	3 (9.7)	2 (8.0)
Ulcer healing (n = 45)	16/24 (66.7)	18/21 (85.8)
Death	9 (29.1)	6 (24.0)

CLI = critical limb ischemia; SD = standard deviation; ABI = ankle-brachial index; $TcPO_2$ = transcutaneous oxygen tension; rePTA = repeat percutaneous transluminal angioplasty

* *p*-value <0.05 indicates statistical significance

related death or acute vessel thrombosis was observed in any patient in the present study, and no patients required emergent surgical intervention.

At one year, the limb salvage rate was 95%. Three patients (5%) underwent major amputation, with one below-knee and two above-knee amputations. Complete wound healing at one year was observed in 76% of patients who presented with non-healing ulcers. At one year, the median time-to-amputation was 53 days after endovascularization. At one year, clinically-driven repeat PTA [rePTA] with DES placement was performed in two patients (3.6%) due to the development of additional occlusions below the stent sites. However, no in-stent restenosis was documented in either of these two patients. At one year, there were 12 (21.5%) deaths. Cause of death in all 12 cases was unrelated to the PTA procedure. Causes of death included cardiac arrhythmia, congestive heart failure, myocardial infarction, and sepsis, with a median time-to-death of 246 days after PTA. In the present study, death was an outcome that adversely affected limb salvage, and this may have caused survival bias. By combining death and major amputation outcomes, 75% of amputation-free survival at follow-up time was 385 days, as shown in Figure 1.

Long-term patency after below-the-knee DES was also demonstrated in the present study. The median follow-up time in the present study was 349 days. In the 67 CLI patients that survived more than one year, limb salvage was 100% during follow-up. Clinically-driven repeat BTK intervention occurred in three patients (6.6%). Of these three patients, one patient had prior isolated BTK DES, and the other two patients had prior concomitant above, and BTK disease intervention. There were no additional major amputations during

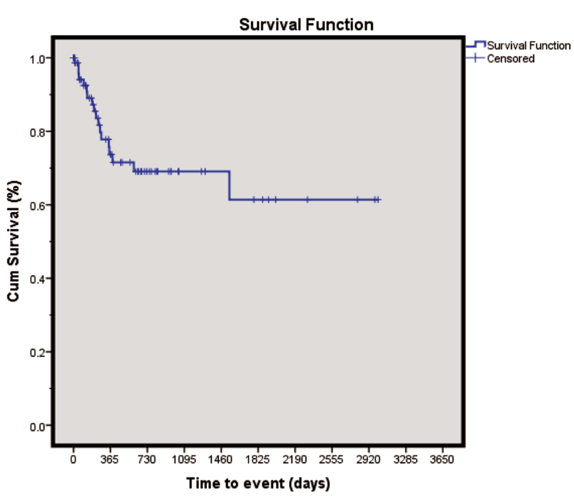

Figure 1. By combining death and major amputation outcomes, 75% of amputation-free survival at follow-up time was 385 days.

the follow-up period. Three additional patients expired after the 1-year follow-up time point.

The authors also analyzed factors that predicted complete wound healing at the 1-year follow-up time point. Sirolimus-eluting stent demonstrated better wound healing efficacy than biolimus-eluting stent at one year. Baseline clinical characteristics, type of lesion before the procedure (stenosis versus occlusion), number of stents are shown in Table 4. However, improvement in baseline versus post-procedural ABI, and improvement in baseline versus post-procedural $TcPO_2$ were shown to be significant predictors of complete wound healing at one year (Table 5).

Table 4. Analysis for factors that predict complete wound healing at 1-year post-procedure

Analysis for factors that predict complete wound healing at 1-year post-procedure	1-year complete wound healing (n = 34)	1-year without complete wound healing (n = 11)	*p*-value
DM, n (%)	33 (97.1)	9 (81.8)	0.143
HTN, n (%)	32 (94.1)	10 (90.9)	1.000
DLP, n (%)	30 (88.2)	6 (54.5)	0.028*
CAD, n (%)	18 (52.9)	9 (81.8)	0.156
Smoker, n (%)	8 (23.5)	1 (9.1)	0.416
Lesion type, n (%)			0.736
Stenosis	15 (44.1)	4 (36.4)	
Occluded	19 (55.9)	7 (63.6)	
Type of stent, n (%)			
Sirolimus	17 (50.0)	2 (18.2)	0.086
Paclitaxel	1 (2.9)	0 (0.0)	1.000
Biolimus	8 (23.5)	8 (72.7)	0.009*
Zatarolimus	1 (2.9)	1 (9.1)	0.433
Everolimus	8 (23.5)	0 (0.0)	0.169
Number of stent, median (min-max)	2 (1 to 12)	2 (1 to 6)	0.446

DM = diabetes mellitus; HTN = hypertension; DLP = dyslipidemia; CAD = coronary artery disease

* *p*-value <0.05 indicates statistical significance

Table 5. Baseline versus post-procedural ABI and $TcPO_2$ at 1 year with and without complete wound healing

Baseline and post-procedural ABI and $TcPO_2$ at 1 year	1-year complete wound healing (n = 34), mean ± SD	1-year without complete wound healing (n = 11), mean ± SD
Baseline ABI	0.74±0.18	0.41±0.03
Post ABI	0.88±0.26	0.98±0.42
p-value	0.040*	0.288
Baseline $TcPO_2$	18.09±11.77	29.75±15.58
Post $TcPO_2$	34.45±14.24	43.75±6.94
p-value	0.015*	0.180

ABI = ankle-brachial index; $TcPO_2$ = transcutaneous oxygen tension

* *p*-value <0.05 indicates statistical significance

Discussion

In the present study, the authors demonstrated the efficacy of PTA with DES placement in patients with CLI, and the efficacy of ABI and $TcPO_2$ as predictors of limb salvage outcomes at 1-year post-PTA in patients treated with DES placement for below-the-knee CLI. At one year, limb salvage was 95%, and complete wound healing was 76%. In patients who survived more than one year, limb salvage remained 100% at a median follow-up of 349 days.

The management of CLI remains challenging. With a very high mortality rate of 25% and 32% at 12 and 24 months after diagnosis of CLI, respectively, the goals of treatment are pain relief, wound healing, and limb preservation[2,3]. Recently, Todoran et al[17] reported higher cardiovascular mortality and amputation risk among CLI patients, when compared with intermittent claudication patients. This higher risk among CLI patients is likely attributable to more intensive treatments that are required for atherosclerotic risk modification, such as revascularization[17]. In the past, surgical bypass was the main revascularization therapy. However, some CLI patients have multiple comorbidities that can lead to a high number of complications, including death[18,19]. Moreover, a lack of anatomically suitable blood vessels can limit the role of surgical bypass in CLI patients. As a result, over the past decade, treatment of CLI has shifted toward PTA therapy[20-24]. Due to similar rates of amputation-free survival and health-related quality of life between patients who underwent bypass surgery and balloon angioplasty, endovascular therapy was found to result in lower short-term morbidity and shorter length of hospital stay[4,6]. With the use of a BMS during PTA, the limb salvage rate after one year was more than 90%[7]. However, subsequent studies reported 1-year re-stenosis rates that ranged from 20% to 60% after BMS placement[8-11]. As a result, the use of DES has received more attention in subsequent studies, as they were found to be associated with lower re-stenosis rates in patients with atherosclerotic heart disease. In 2005, Siablis et al found and reported lower in-stent and in-segment binary re-stenosis rates at 6 and 12 months after sirolimus-eluting stent placement when compared with BMS[10,25]. A 2009 meta-analysis of 18 studies of 640 CLI patients showed the superiority of sirolimus-eluting stent over BMS in terms of higher primary patency rate and lower risk of re-stenosis[9].

According to TASC II guideline, $TcPO_2$ measurement of less than 30 mmHg is defined as one of the objective criteria for CLI[3]. Diabetic patients tend to have more infrapopliteal CLI than non-diabetic patients, as evidenced by the presence of DM in 84.7% of patients in the present study. ABI measurement alone may not be reliable in diabetic patients due to medial calcification of vessels. Moreover, successful revascularization with residual stenosis of less than 30% does not necessarily ensure increased tissue oxygenation. Recently, $TcPO_2$ measurement was found to be a reliable predictor of limb salvage and wound healing after infrageniculate angioplasty in diabetic patients[12,16]. As $TcPO_2$ can reflect both microvasculature circulation and tissue oxygenation improvement, the authors decided to use both ABI and $TcPO_2$ measurement in the present study.

In the present study, the authors focused on limb salvage in CLI patients after below-the-knee DES placement. DES placement at BTK level was found to be an effective therapy in the present study, with a rate of limb salvage at one year of 95%, which is consistent with rates reported from other studies[26-32].

Ferraresi et al[33] reported significant improvement in $TcPO_2$ in 101 patients after PTA in BTK vessels. In that study, target vessel restenosis [TVR] that required rePTA occurred in 42% of patients by the 1-year time point. The present study showed similar results in terms of improving $TcPO_2$, but clinically driven TVR occurred in only 2.5% of cases in the present study. This finding emphasizes the benefit of DES over PTA in BTK lesions.

Data on surgical revascularization at our center revealed a limb salvage rate of 76.6% and a major amputation rate of 16.9%[34]. Moreover, the feasibility of surgical revascularization was only 53% in overall patients due to poor general medical status and lack of patency of distal arteries. PTA with DES placement was reported to be safe, with a rate of overall minor complications of only 3.8% and no procedure-related mortality. Surgical bypass, however, had an 8.2% rate of procedure-related mortality. In the present study, the authors found overall improvement in ABI, but we also found improvement in ABI among subjects with isolated below-the-knee DES placement. This finding confirmed the usefulness of infragenicular DES placement. Below-the-knee DES placement was also found to significantly improve the $TcPO_2$, which improved ulcer healing, as evidenced by 76% complete ulcer healing and 95% limb salvage at the 1-year time point in the present study. Improvement in baseline versus post-procedural $TcPO_2$ was able to predict complete wound healing at one year. The reintervention rate was 31% in the Iida et al[35] study, since only PTA was used. The reintervention rate in the present study was considerably lower at 3.6% at one year, and 9.0% at a median follow-up of 349 days due to better long-term patency of DES as compared to PTA alone. There are many factors that affect wound healing, including the number of vessels that undergo angioplasty or stent placement, the quality of the run-off vessels, angiosome correlations, and the long-term patency of the artery according to the type of drug used in the DES. In the present study, the authors found that sirolimus may have an advantage over biolimus in terms of complete wound healing at one year. Everolimus showed a possible trend towards significance; however, the sample size in the present study may have been too small to identify all possible statistically significant associations and differences. Direct measurement of blood flow and tissue oxygenation as measured by ABI and $TcPO_2$ was shown to be effective for predicting limb salvage outcomes in patients treated with DES for below-the-knee CLI in the present study.

Limitation

The present study has some mentionable limitations. First, this was a non-randomized, retrospective study with a relatively small number of subjects. Second, most subjects were referred from a vascular clinic due to high-operative risk and/or lack of suitable anatomic vessels. It could, therefore, be argued that the present study was influenced by selection bias relative to number and type of comorbidities and severity of peripheral vascular disease. Third, since $TcPO_2$ measurement was only performed in patients with ulcer(s) (Rutherford category 5-6), the authors were not able to collect $TcPO_2$ measurement data for every subject. Finally, Siriraj Hospital is Thailand's largest tertiary referral hospital, which means that the authors have often referred patients with complicated and intransigent conditions that may be more severe than patients with the same condition in other settings.

Conclusion

The results of the present study confirm the efficacy of endovascular treatment with DES placement for treatment of CLI in patients for whom surgical bypass is contraindicated, with excellent limb salvage rate and good wound healing. Regarding the efficacy of ABI and $TcPO_2$ as predictors of limb salvage outcomes in patients treated with DES for below-the-knee CLI, both ABI and $TcPO_2$ were significantly improved after PTA. A large multi-center randomized controlled trial is warranted to determine the role of ABI and

$TcPO_2$ measurement as a new index for evaluating for successful revascularization.

What is already known on this topic?

CLI leads to high morbidity and mortality. Left untreated, CLI can result in major amputation in 30% of patients within one year. Some CLI patients, especially those with DM and/or end-stage renal disease, may have BTK involvement. These patients could be difficult to treat due to a lack of suitable vessels for bypass conduits and inadequate sites for distal anastomosis.

What this study adds?

The findings of the present study confirm the efficacy of endovascular treatment with DES placement for treatment of CLI, and they demonstrate that ABI and $TcPO_2$ are significant predictors of limb salvage outcomes in patients treated with DES for below-the-knee CLI.

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Potential conflicts of interest

The authors declare no conflict of interest.

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