Direct transpedal pressure measurement during transpedal below-the-knee interventions in critical limb ischemia

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Abstract
Aim: The aim of this study was to assess the feasibility of the distal pressure measurement during transpedal below-the-knee interventions in chronic limb-threatening ischemia (CLTI) and to assess the hemodynamic response after percutaneous transluminal angioplasty.

Methods: The clinical and angiographic data of 137 consecutive patients treated via transpedal access in CLTI (Rutherford 4–6) were evaluated. Distal pedal pressure (PP) at the end of the pedal sheath was measured and the pedal-to-aortic pressure index (PAPI) was also calculated before and after the intervention.

Results: Good angiographic results was achieved in 131 patients (95.6%) in the femoro-popliteal and at least in one below-the-knee artery. Significant differences were found in PP and PAPI between before- and after-intervention values (103.2 ± 41.6 mmHg vs. 138.2 ± 37.8 mmHg and 0.74 ± 0.29 vs. 1.03 ± 0.34), respectively. Post-procedural PP and PAPI were significantly higher in patients who underwent good and borderline/unsuccessful intervention 141.7 [135.8–147.6] versus 82.6 [33.8–131.5] mmHg and 1.05 [1–1.1] versus 0.53 [0.2–0.8], respectively. PP's are significantly different in various Rutherford classification groups. Among the studied parameters, postprocedural PAPI was found to have the best discriminatory power to predict 3-month amputation (c-statistic: 0.749, 95% CI: 0.546–0.952, p = .016, sensitivity: 57.1%, specificity: 92.3% using the cut-off criterion ≤0.58). Major adverse event was detected in 17 patients at 3 months follow up (12.4%), including 7 major amputations (5.1%).

Conclusion: Transpedal pressure and pedal-to-aortic pressure index significantly increased during transpedal below-the-knee angioplasty and final pressure and index correlates significantly with limb salvage.

Abbreviations: ABI, Ankle-brachial index; BTK, below-the-knee; CLTI, chronic limb-threatening ischemia; DPU, Doppler perfusion units; FP, femoro-popliteal; FFR, fractional flow reserve; stress FFRperiph, peripheral fractional flow reserve; TBPI, toe-brachial pressure index; LL, lesion length; MLD, minimum lumen diameter; PAPI, pedal-to-aortic pressure index; PP, pedal pressure; PTA, percutaneous transluminal angioplasty; DS, percent diameter stenosis; RVD, reference vessel diameter; tcO2, transcutaneous O2 pressure.

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1 | INTRODUCTION

Chronic limb threatening ischemia (CLTI) is associated with high rate of amputation and long term adverse events rate, but with successful percutaneous transluminal angioplasty the amputation rate can be reduced. Hemodynamic assessment in CLTI can be non-invasive and invasive. Non-invasive parameters are the ankle-brachial index (ABI), toe-brachial pressure index (TBPI), laser Doppler measurements (Doppler Perfusion Unit (DPU) and transcutaneous O$_2$ saturation (TcO$_2$)). Invasive parameters are the quantitative angiographic measurements, angiographic wound blush, flow assessment and direct pressure measuring by pressure wire. As described in detail in a previous study, CLTI is associated with an ankle systolic pressure of 50 mmHg or less or a toe systolic pressure of 30 mmHg or less. Generally, a TBPI of less than 0.75 is predictive of the presence of hemodynamically significant peripheral artery disease and the change in ABI $\geq$ 0.23 and TBI $\geq$ 0.21 was an independent predictor of wound healing. By pressure wire measurement the post procedural fractional flow reserve (FFR) value of $>0.66$ was the best predictor of wound healing. Transpedal access for below-the-knee (BTK) and superficial femoral artery (SFA) interventions has been introduced in bail-out cases, and they give an opportunity to access the direct pressure during CLTI interventions. The aim of this study was to assess the feasibility of the distal pressure measurement during transpedal interventions in critical limb ischemia and to assess the hemodynamic response after percutaneous transluminal angioplasty.

2 | METHODS

2.1 | Study population

We prospectively enrolled 137 consecutive patients in a multi-center trial with CLTI and angiographically proven BTK stenosis. Institutional Review Committee approved the study at all sites, and all patients provided written informed consent prior to study inclusion. Rutherford criteria was investigated in all patients, but WIfI score and laser Doppler was not recommended in the study.

Inclusion criteria were: CLTI (Rutherford 4–6) and angiographically proven significant lesion of the distal lower limb (DS $> 69\%$). Exclusion criteria were: infected or wounded distal puncture point, that makes the puncture impossible or risky, poor distal run-off below the puncture zone and non-viable distal lower limb.

2.1.1 | Antithrombotic regimen

After a loading dose of 325 mg aspirin and 300 mg clopidogrel, the patients who underwent stenting received dual antiplatelet therapy (aspirin 100 mg and clopidogrel 75 mg) for 2 months. Patients who underwent only balloon angioplasty (PTA) were treated with life-long aspirin. In addition, 5,000 IU heparin sodium, and 250 mcg nitroglycerine was administered directly to the radial artery through the sheath. Additional Na-Heparin was given until reaching 100 IU/kg. Routine ACT was not measured during the intervention.

2.1.2 | Angioplasty strategy

In multi-level lesions the SFA or the popliteal artery was optimized first and second the BTK segment, however in BTK chronic total occlusions, the BTK lesion was dilated first to facilitate device advancement. In isolated BTK lesions, the direct retrograde access was preferred, but in some multivessel dilatations or plantar arch reconstructions, pedal to pedal cross over was done using angulated CX support catheter (Cook Co).

2.1.3 | Angioplasty

The diagnostic angiography was done from transradial access with a 125 cm long pigtail catheter (Figure 1). The transpedal access was done by ultrasound guidance (Vivid, General Electric) with a Terumo radial needle (Terumo, Japan). After successful puncture, the transpedal artery

FIGURE 1  A 72-year-old female patient with lower limb gangrene. (a) Transradial DSA shows long critical anterior tibial artery lesion and posterior tibial artery occlusion. (b) Transpedal angiography and pedal pressure measurement (PP: 60/40 mmHg, PAPI 0.46) and (c) balloon angioplasty with a long 2.5 $\times$ 210 mm balloon and (d) final transradial DSA and pedal pressure measurement shows no flow limiting stenosis and improved hemodynamics (PP: 160/80 mmHg, PAPI 1.10)
was cannulated with a dedicated 4F transpedal cannula (Cook) and the lesion was passed by a 0.014” guidewire. In sheathless cases the procedure was done after removing the transpedal cannula, but in trans-sheath cases, a 4F Terumo transradial sheath was used for the intervention and for transpedal pressure measurements (Terumo, Japan). After balloon angioplasty, the lesion was stented only in flow limited dissections in the BTK segment. After final transpedal angiography and pedal pressure (PP) measurement, the sheath was removed and non-occlusive pressure has been applied. Final flow has been assessed always with Doppler ultrasound measurement.

2.2 | Angiographic findings

Peripheral angiography was performed from transradial access following the routine procedure. For qualitative angiographic measurements, the 5F diagnostic catheter was used for calibration. Vessels and lesions were analyzed using a quantitative computerized analysis (QCA) system (Innova 3100, General Electric Healthcare). Reference vessel diameter (RVD), percent diameter stenosis (DS) and lesion length (LL) were measured before and after angioplasty.

2.3 | Pressure measurements and pedal-to-aortic pressure index calculation

Pressure measurements were performed as described. Following peripheral angiography, a transpedal 4F sheath was advanced in the transpedal artery and direct pressure measurement was done. Aortic pressure was measured from the pigtail catheter in the aorta. All patients received intravenous heparin at doses determined according to body weight. The following measurements were taken before and after the procedure: PP and resting transpedal pressure/aortic pressure (PAPI).

2.4 | Doppler ultrasound and non-invasive pressure measurements

Peak systolic velocity (PSV) was measured in the distal segments before the puncture. ABI and TBPI measurement was optional in the study.

2.5 | Follow-up

The follow-up included a clinical examination at 3 months after intervention.

2.6 | Endpoints and definitions

Clinical success: Primary clinical success was defined as an improvement in at least one clinical category in the Rutherford-Becker classification at the 2-month follow-up. Technical success: Technical success was defined as PTA resulting in less than 30% residual stenosis with sufficient anterograde flow. Accordingly, a suboptimal result was defined as sluggish flow and/or residual stenosis of 30–50% after repeated dilatation.

2.6.1 | Angiographic result

Good angiographic result if PTA resulting in less than 30% residual stenosis with sufficient anterograde flow. Borderline angiographic result if PTA resulting sluggish flow and/or residual stenosis of 30–50%. Unsuccessful angiographic result if PTA resulting lesion residual stenosis more than 50%.

Limb salvage: was defined as prevention of any amputation.

Major amputation: was defined as limb loss below or above the knee level, while minor amputation was defined as an amputation to distal from the trans-metatarsal level.

2.6.2 | Major adverse events

The major adverse events (MAEs) assessed were death, nonfatal acute myocardial infarction, repeat revascularization of the target vessel by PTA or artery bypass graft operation or major amputation during the hospital stay and at 2 months of follow-up.

2.6.3 | Vascular complications

Major vascular complications were defined as diminished or lost arterial pulse or the presence of any pseudoaneurysm or arteriovenous fistula following the procedure or during clinical follow-up. Minor vascular complication was defined as hematoma of ≥5 cm in diameter over the femoral puncture area that did not require further treatment. Bleeding complication was defined as any bleeding with a fall in hemoglobin level of >3 g/dl requiring blood transfusion.

| TABLE 1 | Demographic and clinical data |
|----------|-------------------------------|
| Demographic and clinical data n (%) | Age (years) | 69.6 [67.8–71.4] |
| | BMI (kg/m²) | 16.73 [27.2–29.5] |
| | Male | 86 (67.8%) |
| | Hyperlipidemia | 75 (57.4%) |
| | Hypertension | 122 (89%) |
| | Smokers | 35 (25.5%) |
| | Coronary artery disease | 66 (48.2%) |
| | Diabetes mellitus | 56 (41%) |
| | Renal insufficiency | 38 (27.7%) |
| Rutherford classification | II4 | 78 (56.9%) |
| | III5 | 22 (16.1%) |
| | III6 | 37 (27%) |
2.7 Statistical analysis

All statistical analyses were performed with Graph Pad Prism 8. Continuous variables are presented as the mean ± SD or mean and interquartile ratio, as appropriate. Differences between continuous variables were analyzed using Student’s t test or Mann–Whitney test, as appropriate. Correlation was calculated with Spearman statistical analysis. We evaluated predictive capacity of various pressure parameters measured before and after the intervention on occurrence of amputation at 3 months by receiver operating characteristic (ROC) curve analysis. Distributions of the parameters among the classes was also assessed graphically using box plots. Because of the small sample size, we constructed bootstrapped percentile confidence intervals for the area under the ROC curve (AUC) analysis using 10,000 samples yielding more robust results than the conventional non-parametric method. Moreover, because of the low number of the events and imbalance of the data set (ie, numbers of controls and cases differ substantially with an event rate of 5.11%) which are known circumstances that may cause overestimation of predictive performance during ROC analysis, we also constructed precision-recall curves that are more appropriate for imbalanced data sets like the present one, since the calculations do not make use of the true negatives, they are only concerned with the correct prediction of the less frequent

### TABLE 2 Procedural data

| Angioplasty |  |
|-------------|---|
| Femoro-popliteal segment, n | 49 |
| Balloon angioplasty, n (%) | 49 (100%) |
| Stent implantation, n (%) | 22 (44.9%) |

| Below-the-knee segment, n | 137 |
| Balloon angioplasty, n (%) | 155 (100%) |
| Stent implantation, n (%) | 26 (19%) |

| Primary access site for intervention |  |
|-------------------------------------|---|
| Anterior tibial artery | 115 (83.9%) |
| Posterior tibial artery | 15 (0.11%) |
| Peroneal artery | 7 (5.1%) |

| Access site for angiography |  |
|----------------------------|---|
| Radial artery access | 76 (55.5%) |
| Femoral artery access | 3 (21.9%) |
| No angiographic guidance | 58 (42.3%) |

| Procedural related factors |  |
|--------------------------|---|
| Procedure time (min) | 45.5 [29.2–60] |
| Fluoroscopy time (sec) | 720.8 [325.1–929.5] |
| Dose area product (Gy/cm²) | 11.71 [3.1–14.7] |
| X-ray dose (mGy) | 65.5 [27.1–77.5] |
| Contrast consumption (ml) | 78.8 [35–110] |

| Multilevel intervention, n (%) | 49 (35.7) |
| Isolated below-the-knee disease, n (%) | 88 (64.3) |
| Single intervention, n (%) | 53 (60.2) |
| Parallel interventions, n (%) | 35 (39.8) |

| Procedural success |  |
|-------------------|---|
| Good angiographic result, n (%) | 131 (95.6) |
| Not successful or borderline, n (%) | 6 (4.4) |

### TABLE 3 Angiographic and pressure measurements

| Angiographic measurements | Before intervention | After intervention |
|---------------------------|---------------------|-------------------|
| Superficial femoral artery lesions (n = 35) |  |
| Diameter stenosis (%) | 81.4 [71.5–91.3] | 10.3 [5.9–14.6]** |
| Reference diameter (mm) | 5.1 [4.7–5.4] |  |
| Lesion length (mm) | 110.7 [83.3–137.6] |  |
| CTO in SFA segment (%) | 17 (48.6%) |  |

| Popliteal artery lesions (n = 38) |  |
| Diameter stenosis (%) | 89.4 [84.0–94.8] | 19.7 [11.6–27.8]** |
| Reference diameter (mm) | 4.6 [4.3–4.8] |  |
| Lesion length (mm) | 77.7 [60.4–94.9] |  |
| CTO in popliteal segment (%) | 18 (47.3%) |  |

| Tibial artery lesions (n = 141) |  |
| Diameter stenosis (%) | 90.9 [88.6–93.2] | 15.5 [11.9–19.1]** |
| Reference diameter in tibial arteries | 2.6 [2.5–2.6] |  |
| Lesion length (mm) | 88.9 [73.0–104.7] |  |
| CTO in tibial segment (%) | 56 (39.7%) |  |

| Pressure measurements |  |
|----------------------|---|
| Aortic pressure (mmHg) | 141.2 ± 27.1 | 139.8 ± 26.1 |
| PP (mmHg) | 103.2 ± 41.6 | 138.2 ± 37.8 ** |
| PAP (pedal pressure/aortic pressure) | 0.74 ± 0.29 | 1.03 ± 0.34 ** |

| Successful (n = 131) |  |
|----------------------|---|
| PP | 104.4 [97.3–111.5] | 141.7 [135.8–147.6]** |
| PAPI | 0.75 [0.7–0.8] | 1.05 [1–1.1]** |

| Unsuccessful or borderline result (n = 6) |  |
|------------------------|---|
| PP | 78.3 [26.8–129.8] | 82.6 [33.8–131.5] |
| PAPI | 0.5 [0.2–0.8] | 0.53 [0.2–0.8] |

| Amputated patients (n = 7) |  |
|---------------------------|---|
| PP | 72.4 [25.8–119] | 101.7 [60.8–142.6]* |
| PAPI | 0.49 [0.18–0.80] | 0.71 [0.42–1]* |

| Non-amputated patients (n = 130) |  |
|-------------------------------|---|
| PP | 104.9 [97.8–112.0] | 140.1 [127.1–141.8]** |
| PAPI | 0.76 [0.7–0.8] | 1.04 [0.97–1.1]** |

Abbreviations: CTO, chronic total occlusion; SFA, superficial femoral artery.

*p < .05.

**p < .001.
positive events. Area under the precision-recall curves (PRAUC) was calculated using the interpolation of Davis and Goadrich to avoid overestimation of the area using linear interpolation. A two-tailed P value less than .05 was considered statistically significant. Computations were performed with R version 3.6.0 (R Foundation for Statistical Computing, Vienna, Austria).

| TABLE 4 | Pressure measurements and clinical outcome by Rutherford classification |
|----------|-------------------------------------------------------------------------|

| Pressure measurements | Rutherford 4 (n = 78) | Rutherford 5 (n = 22) | Rutherford 6 (n = 37) |
|-----------------------|-----------------------|-----------------------|-----------------------|
| PP                    | Before intervention   | 109.7 ± 35.1          | 118.3 ± 43.9          | 80.6 ± 45.4**         |
|                       | After intervention    | 148.7 ± 29.7          | 142 ± 35.4            | 113.5 ± 43.9**        |
| PAPI                  | Before intervention   | 0.82 ± 0.2            | 0.78 ± 0.33           | 0.57 ± 0.3**          |
|                       | After intervention    | 1.14 ± 1.3            | 0.95 ± 0.26           | 0.82 ± 0.35**         |
| Amputation rate, n (%)| 1 (1.2)               | 0 (0)                 | 7 (18.9)*             |

Abbreviations: PAPI, pedal to aortic pressure index; PP, pedal pressure.
*p < .05.
**p < .001.

| TABLE 5 | Perioperative complications |
|----------|----------------------------|

| Procedural complications | n (%) |
|--------------------------|-------|
| Access site complications |       |
| Radial punctures, n      |       |
| Minor                    | 2 (1.4) |
| Major                    | 0 (0)   |
| Pedal punctures, n       |       |
| Major or minor           | 0 (0)   |
| MAE at 3-month FU in all patients |       |
| Death, n (%)             | 5 (3.6) |
| Major amputation, n (%)  |       |
| Femoral                  | 7 (5.1) |
| Crural                   | 2 (1.4) |
| Re-PTA, n (%)            | 5 (3.6) |
| Myocardial infarction, n |       |
| 1 (0.7)                  |       |
| Stroke, n (%)            | 3 (2.2) |
| Summary (all events), n (%) | 19 (13.8) |
| Summary (at least one event), n (%) | 17 (12.4) |

Abbreviations: MAE, major adverse events; PTA, percutaneous transluminal angioplasty.

3 | RESULTS

3.1 | Demographic and clinical data

The clinical indication of the procedure was rest pain in 78 patients (56.9%), arterial ulcer in 22 cases (16.1%) and gangrene in 37 patients (27%) (Table 1).

3.2 | Procedural data

The intervention was performed with good angiographic results in 131 patients (95.6%). Balloon angioplasty was done in all cases (100%), and additional stent implantation was indicated in 22 cases (44.9%) in the femoro-popliteal (FP), and 26 cases (19%) in the BTK...
segment. Complete wound healing has been achieved in 49/59 (83%) of patients with Rutherford 5–6 criteria at 3 months follow-up (Table 2).

3.3 | Angiographic and pressure measurements

After the procedure, the percent DS had improved from 81.4% [71.5–91.3] to 10.3% [5.9–14.6] in the SFA, from 89.4% [84.0–94.8] to 19.7% [11.6–27.8] in the popliteal and from 90.9% [88.6–93.2] to 15.5% [11.9–19.1] in the tibial arteries (Tables 3 and 4). From before to after the operation, PP improved from 103.2 ± 41.6 to 138.2 ± 37.8 (p < .001), and PAPI improved from 0.74 ± 0.29 to 1.03 ± 0.34 (p < .01) (see Figure 2). PP and PAPI has been improved significantly in patients with good angiographic result (PP from 104.4 [97.3–111.5] mmHg to 141.7 [135.8–147.6] mmHg (p < .001) and PAPI from 0.75 [0.7–0.8] to 1.05 [1–1.1] (p < .001), but not in patients with borderline or unsuccessful (PP from 78.3 [26.8–129.8] mmHg to 82.6 [33.8–131.5] mmHg (p = ns) and PAPI from 0.5 [0.2–0.8] to 0.53 [0.2–0.8] (p = ns). Pressure measurements in different Rutherford groups are summarized in Table 4 and Figure 2. Parallel artery CTO was not associated with significantly lower PP (107.1 [94.3–119.9] vs. 100.8 [92.4–109.1] mmHg) or PAPI (0.76 [0.68–0.85] vs. 0.73 [0.66–0.79]). Significant correlation was found between PP and ABI (r: 0.34, p = .01, CI: 0.07–0.56) and between PAPI and ABI (r: 0.31, p = .02, CI: 0.037–0.54).

3.4 | Perioperative complications

Major procedural complications were not detected (Table 5). Radial access site complications were observed in 2 patients (1.5%) (two asymptomatic radial artery occlusions). Pedal artery vascular complications were not detected. The cumulative incidence of MAE at 3-month follow-up was 10.2% and all patients without major events reached the follow-up time. The cumulative incidence of major and minor amputation at 3-month follow-up was 5.8 and 6.5%, respectively. The incidence of 3-month mortality in patients who underwent major amputation was significantly higher than in patients with limb salvage (2/8 patients (25%) vs. 7/128 patients (5.5%) (p < .05)). Final PAPI value ≤0.58 (AUC: 0.749, sensitivity 57.1%, specificity 92.3%) had the best cut-off value to predict freedom from 3-month amputation rate (Figures 3 and 4). Final PP value ≤108 mmHg (AUC: 0.74, sensitivity 71%, specificity 83%) was associated to predict freedom from 3-month amputation rate (Figures 3 and 4).

**FIGURE 3** Distributions of the investigated pressure parameters according to outcome class at 3 months. Left panel: pedal-to-aortic pressure index (PAPI). Right panel: pedal systolic blood pressure (SBP) after the intervention. In the box-and-whisker plots the box shows the median and interquartile range (IQR), while the whiskers extend to the most extreme data point which is no more than 1.5 times the IQR from the box. Median pedal-to-aortic pressure indices were different: 1.01 (IQR 0.84–1.21) among cases with no amputation and 0.58 (IQR 0.46–1.00) in patients with amputation at 3 months, median difference 0.43, 95% confidence interval (CI) 0.04–0.84, p = .0247, according to the exact Wilcoxon–Mann–Whitney test. Similarly, median post-procedural pedal SBP was 145 mmHg (IQR 120–160 mmHg) and 106 mmHg (IQR 64–133 mmHg), respectively, median difference 43 mmHg, 95% CI 3–75 mmHg, p = .0333 (exact Wilcoxon–Mann–Whitney test). Dashed lines represent the cut-off values: PAPI: ≤0.58, pedal SBP: <108 mmHg (for details, see text) [Color figure can be viewed at wileyonlinelibrary.com]
Our study is the first study describing the feasibility and safety of the PP measurement in CLTI. In this prospective, consecutive series of patients, we demonstrate several important findings: (a) the PP measurement is reliable before and after intervention; (b) successful intervention results in increased PP and PAPI value; (c) PP and PAPI value is different in different Rutherford groups (d) final PP and PAPI effects long term limb survival.

4 | Discussion

Hemodynamic assessment in CLTI

Anatomical distribution of CLTI is multi-level or isolated BTK arterial disease. The diagnosis of CLTI is straightforward and is based on vascular examinations, including measurement of the ABI and TBPI and a number of imaging modalities, but all of these examinations have limitations; thus, the gold standard for CLTI diagnosis is still digital subtraction angiography (DSA). DSA clearly depicts the anatomy of the
TCPo2, TcpCO2 and DPU are established indicators of local cutaneous ent pathophysiological mechanism. Distal pressure, Pd/Pa and FFR measurement in the BTK region is feasible, the papaverine induces significant decrease and a peak systolic gradient of 10 mmHg. The criteria utilize a mean gradient of 15 mmHg before or after vasodilation. There is no consensus on the diagnostic translesional pressure gradient criteria, but the most widely accepted criteria utilize a mean gradient of 15 mmHg before or after vasodilators and a peak systolic gradient of 10–20 mmHg. Banerjee S et al found that translesional gradient measured using a pressure wire after administration of 100 μg of adenosine was strongly correlated with rest ABI (r = −0.748); exercise ABI (r = −0.888), exercise duration (r = −0.711), and percent angiographic stenosis (r = −0.818) (p < .01 for all). Our working group reported that pressure wire measurement in the BTK segment is feasible, the papaverine induces significant hyperemia, and the pressure wire measurement significantly improves the diagnostic accuracy. BTK wedge pressures were significantly higher in rest pain or crural ulcer than gangrene (46.3 ± 34.4 vs. 40.1 ± 26.6 vs. 28.5 ± 26.6 mmHg, p < .05) which represents a different pathophysiological mechanism. Distal pressure, Pd/Pa and FFR periph were significantly correlated with %TCPo2 and DPU. Too pressure was significantly correlated with distal pressure, Pd/Pa and FFRperiph (r: -0.30, r: 0.37 and 0.33 [p < .05], respectively). Our transpedal pressure measurement study confirmed this finding, that the mean transpedal pressure is lower in the Rutherford stage 6 class, than in the Rutherford stage 4–5 class (see Table 4). Postprocedural PP and PAPI was lower in patients with major amputation at 3 months (see Table 3). Among the studied parameters, postprocedural PAPI was found that final PAPI value ≤0.58 (AUC: 0.749, sensitivity 57.1%, specificity 92.3%) had the best cut-off value to predict freedom from 3-month amputation rate (Figure 4).

4.3 Limitations of the technique

The main limitation of the PP measurement is the small difference between the size of the lumen and the sheath, because larger sheaths obstructs anterograde flow and the measured pressure can be lower than the real pressure. In our study group, the routine sheath size for pressure measurement was 4 French, which theoretically does not affect the flow around the sheath. Another limitation of the technique might be the poor run-off and reduced flow reserve, which can modify the proximal pressure in size, therefore we have excluded these patients from the study.

Potential clinical applications of transpedal pressure measurement are to assess the lesion severity and distal collateral supply before the intervention, to differentiate the pathomechanism of the rest pain and to assess the immediate hemodynamic results after intervention predicting long-term clinical outcomes.

4.4 Study limitations

This was a proof of concept study investigating the feasibility of PP measurement in peripheral arteries in CLTI; however, a moderate number of cases were included in this study, and long-term outcome data are not available at this stage. Another limitation is that WIfI score or TBPI measurement was not applied in the study.14

5 CONCLUSION

Transpedal pressure and pedal-to-aortic pressure index significantly increased during transpedal BTK angioplasty and final pressure and index correlates significantly with limb salvage.

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