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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Physiological indices for evaluating balloon angioplasty outcomes in below-the-knee artery lesions of patients with chronic limb-threatening ischemia

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PURPOSE

To assess the potential use of resting distal pressure/aortic pressure (Pd/Pa) and constant resistance ratio (cRR) physiological indices in the treatment of tibial artery lesions with balloon angioplasty in patients with chronic limb-threatening ischemia (CLTI).

METHODS

In this single-center retrospective study, resting Pd/Pa and cRR measurements were performed using a pressure microcatheter after balloon angioplasty. Procedures were conducted using balloons with diameters of 3 and/or 3.5 mm. The optimal group was defined as patients with either resting Pd/Pa or cRR ≥0.9, whereas the acceptable group included those with both values between 0.8 and 0.9. Clinical improvement in patients with rest pain (Rutherford 4) was defined as at least a 1-point category improvement, indicating a reduction or resolution of rest pain.

RESULTS

The study population consisted of 40 patients (75% men; mean age 64 ± 11.2 years), with a follow-up duration of 92 ± 40.5 days. Foot ulcers were present in 90% of the patients. During follow-up, wound healing was observed in 69.7% of patients. The optimal group exhibited higher rates of wound healing and clinical improvement than the acceptable group, although the difference was not statistically significant (80% vs. 50%, $P = 0.151$). No patient required target vessel revascularization. The overall limb salvage rate during follow-up was 94.6%.

CONCLUSION

Short-term follow-up demonstrated favorable rates of wound healing, patency, and limb salvage. The optimal group showed a trend toward improved wound healing and clinical improvement.

CLINICAL SIGNIFICANCE

This study highlights the utility of resting Pd/Pa and cRR as reproducible physiological indices for objectively evaluating the success of balloon angioplasty in below-the-knee arteries in patients with CLTI. Physiological assessment can guide procedural decisions, contributing to improved limb salvage and high patency rates.

KEYWORDS

Below-the-knee, artery, balloon angioplasty, physiological index, constant resistance ratio

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Peripheral artery disease (PAD), observed in nearly 30% of the elderly population, includes a severe form characterized by ischemic rest pain and tissue loss, known as chronic limb-threatening ischemia (CLTI), which carries high risks of mortality and major amputation. In a considerable proportion of these cases, below-the-knee (BTK) arteries are the primary culprit.[1] The predominant treatment approach for BTK artery disease is percutaneous transluminal angioplasty alone.[2] Although technical success in BTK interventions has tradi-

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tionally been assessed using conventional angiography, recent studies have demonstrated the potential utility of evaluating lumen patency with intravascular ultrasound (IVUS).[3,4] The search for new methods to improve the efficacy of endovascular treatment and to enhance patency and limb salvage rates in BTK artery disease remains ongoing.

In coronary interventions, anatomical optimization methods such as IVUS and functional optimization methods such as fractional flow reserve (FFR) are successfully used for post-procedural assessment. Patients with optimal angiographic results and high FFR values tend to experience better clinical outcomes.[5] In the physiological evaluation of stenoses, the gold-standard FFR–obtained under hyperemia induced by vasodilator agents such as adenosine–has shown good correlation with non-hyperemic parameters such as resting distal pressure/aortic pressure (Pd/Pa), which can be measured without pharmacological agents.[6] Additionally, a novel resting physiological index, the constant resistance ratio (cRR), has shown high diagnostic consistency. It is calculated as the average Pd/Pa value measured during constant-resistance periods across five consecutive resting cardiac cycles.[7]

There are only a few studies related to PAD. Physiological indices obtained after endovascular treatment of iliac and superficial femoral artery stenoses have been found to correlate with clinical improvement.[8] Furthermore, in BTK arteries, physiological parameters have been reported to align with standard morphological parameters.[9]

The present study investigates the potential of resting Pd/Pa and cRR measurements in BTK arteries as effective criteria for assessing the success of balloon angioplasty procedures. We hypothesized that the physiological indices resting Pd/Pa and cRR can objectively reflect the functional assessment of post-procedural vessel patency in the BTK arteries of patients with CLTI, thereby indicating procedural success.

Main points

- Resting distal pressure/aortic pressure and constant resistance ratio measurements appear to be feasible and potentially effective physiological indices for assessing procedural success following below-the-knee (BTK) artery balloon angioplasty in patients with chronic limb-threatening ischemia.
- Optimal post-procedural values (≥0.9) of either physiological index may be associated with improved wound healing and clinical outcomes.
- Performing effective balloon angioplasty with the guidance and support of functional assessment may have contributed to improved wound healing in the present study population, which predominantly consisted of severely calcified and complex BTK artery lesions.

Methods

Study design

This single-center, retrospective study was approved by the Ankara Bilkent City Hospital Medical Research Scientific Ethics Review Board (decision number: TABED 2-25-841, date: 22/01/2025) and conducted in accordance with the principles of the Declaration of Helsinki. Due to its retrospective nature, the requirement for written informed consent was waived by the Institutional Review Board. Patients with CLTI (Rutherford category 4–6) who underwent balloon angioplasty for ≥70% stenosis in BTK tibial arteries, with resting Pd/Pa and cRR measurements between June 2024 and November 2024, were included in the study. Two patients were excluded because they were lost to follow-up. During the same period, participants who underwent digital subtraction angiography (DSA) with resting Pd/Pa and cRR measurements for claudication or foot ulcers but had no major BTK artery stenosis were included in the healthy tibial arteries group (Figure 1).

Procedural steps

A 5F sheath was inserted into the ipsilateral common femoral artery using an antegrade approach, followed by the administration of 70 IU/kg of heparin through the sheath. In patients with an estimated glomerular filtration rate of <60 mL/min/1.73 m^2, imaging from the groin to the ankle was performed using carbon dioxide (CO_2). Stenoses or occlusions in the BTK arteries were crossed using a 0.018-inch guidewire (Gladius, Asahi Intecc, Aichi, Japan). Balloon angioplasty was performed using semi-compliant balloons with diameters of 3 and/or 3.5 mm and lengths of 150 or 200 mm, inflated at pressures ranging from 6 to 12 mmHg for 30 seconds (Minerva, Guangdong, China). In patients with lower body habitus, 3 mm balloons were initially preferred.

In all patients, following pressure microcatheter equalization, the microcatheter was advanced to the ankle over the same guidewire and then slowly pulled back at a constant speed to the tibial artery origin. Physiological indices were measured during this process (TruePhysio pressure microcatheter, Insight Lifetech, Shenzhen, China). No vasodilator agents were administered, and all data were obtained under resting conditions.

Study parameters and follow-up examination

In BTK arteries, the resting Pd/Pa was defined as the ratio of the lowest pressure value

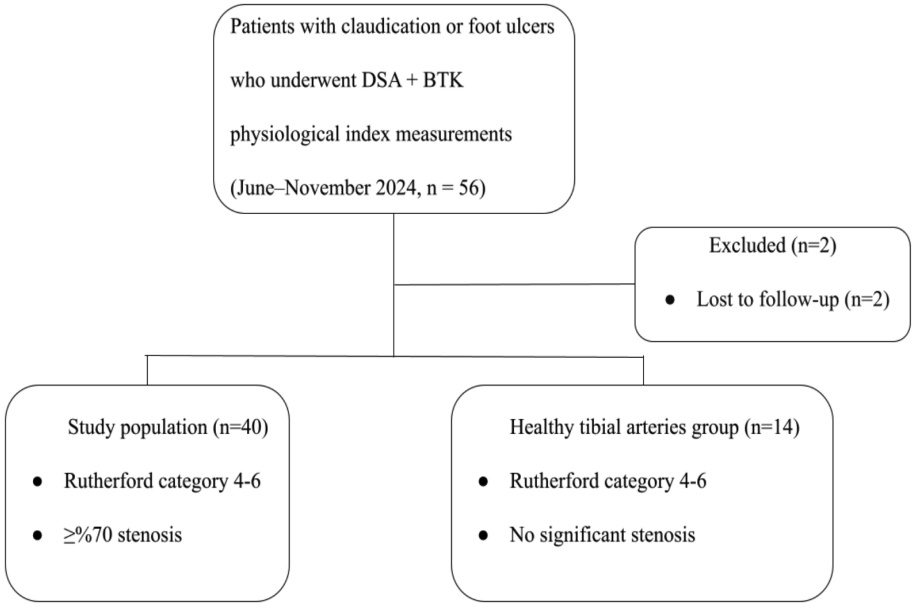

Figure 1. Patient selection flowchart for the study group and the healthy tibial arteries group. DSA, digital subtraction angiography; BTK, below-the-knee.

obtained while the pressure microcatheter was pulled back from the distal tibial artery to its origin, relative to the popliteal artery pressure. A post-procedural resting Pd/Pa and cRR value of >0.8 was targeted. The optimal group was defined as patients with at least one index (resting Pd/Pa or cRR) with a value ≥0.9. A failed procedure was defined as the presence of at least one value ≤0.8. The acceptable group included patients with both resting Pd/Pa and cRR values between 0.8 and 0.9.

The primary endpoint was a composite of complete wound healing in patients with foot ulcers (Rutherford category 5–6) and clinical improvement in patients with rest pain (Rutherford category 4), defined as at least a 1-point improvement in Rutherford category. The secondary endpoint was vessel patency, assessed by Doppler ultrasound during follow-up. At 1st-and 3rd-month follow-up examinations, a peak systolic velocity of <200 cm/s on Doppler ultrasound was considered indicative of no substantial restenosis.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation or median (range). Normality was assessed using the Shapiro–Wilk test. Comparisons of physiological index values in tibial arteries between the study group and the healthy group were performed using the Student's t-test. Wound healing and clinical improvement between patients with optimal and acceptable outcomes were compared using the chi-square test or Fisher's exact test, as appropriate. Student's t-test, Mann–Whitney U test, the chi-square test, or Fisher's exact test was applied, depending on the type and distribution of each variable, to compare baseline characteristics between the optimal and acceptable groups. Three patients who underwent planned amputation and one patient who died before the 1-month follow-up examination were excluded from follow-up analyses. Statistical analyses were performed using SPSS version 26.0 (BM, Armonk, NY, USA), and a *P* value of <0.05 was considered statistically significant.

Results

The study population consisted of 40 patients (75% men; mean age 64 ± 11.2 years), with a mean follow-up duration of 92 ± 40.5 days (Table 1). The healthy tibial arteries group included 14 participants, comprising 18 arteries (85.7% men; mean age 55.5 ± 9.9 years), with 66.7% involving the anterior tibial artery (ATA) and 33.3% the posterior tibial artery (PTA). Foot ulcers were present in 90% of the study patients.

Table 1. Baseline characteristics of the study population (n = 40)

Characteristic	Value
Age, years	64 ± 11.2
Gender, male	30 (75%)
Hypertension	27 (67.5%)
Diabetes mellitus	35 (87.5%)
Chronic kidney disease	18 (45%)
Dialysis	4 (10%)
Coronary artery disease	19 (47.5%)
Cerebrovascular ischemic event	2 (5%)
Dyslipidemia	19 (47.5%)
Smoking, pack × years	20 (range: 0–50)
Current smoker	6 (15%)
Chronic total occlusion	27 (62.8%)
Lesion length, mm	270 (51–335)
Lesion location (PTA/ATA)	17/26
TASC C–D lesions	39 (90.7%)
PACSS 3–4 lesions	30 (69.8%)
Procedure time, min	57.4 ± 15.6
Adjunctive femoropopliteal artery balloon angioplasty	6 (15%)
Iliac artery balloon angioplasty	0 (0%)

Data are presented as mean ± standard deviation, median (range), or number (percentage). PTA, posterior tibial artery; ATA, anterior tibial artery; TASC, Trans-Atlantic Inter-Society Consensus; PACSS, peripheral artery calcification scoring system.

Baseline characteristics were similar between the optimal and acceptable groups (Table 2). At least acceptable outcome values were achieved in all treated cases. Optimal results could not be obtained in 16.3% of the treated arteries due to patients experiencing intolerable pain during balloon angioplasty, which limited the use of larger balloon diameters or higher inflation pressures. A 3.5 mm balloon was directly used in 53.5% of the target vessels, whereas only a 3 mm balloon was used in 14%. In the remaining cases, balloon angioplasty was performed sequentially with 3 mm and then 3.5 mm balloons.

Following balloon angioplasty, resting Pd/Pa and cRR values reached levels comparable to those observed in the healthy tibial arteries group (Table 3). No procedure-related access complications, vascular rupture, flow-limiting dissection, or distal embolization were observed. Final DSA confirmed full patency of the pedal arch in all cases. In 47.5% of the study population, CO_2 angiography was utilized, and only 2 mL of iodinated contrast material–diluted at a 1:4 ratio with saline–was administered for final pedal arch imaging.

Among patients with foot ulcers, complete wound healing was observed in 69.7% during short-term follow-up. The median time to complete wound healing was 45 days (range: 20–150 days). In patients classified as Rutherford category 4, clinical improvement was observed. Although higher rates of wound healing and clinical improvement were noted in the optimal group than in the acceptable group, the difference was not statistically significant (80% vs. 50%, *P* = 0.151).

In three patients, both the ATA and PTA were treated with balloon angioplasty. In one of these patients, the physiological outcome was classified as acceptable, whereas optimal outcomes were achieved in the remaining two. In all cases, the strategy of maintaining at least one straight flow was applied, toward the wound area in patients with ulcers, and toward the foot in those with rest pain.

No substantial restenosis was detected on follow-up Doppler ultrasound, and no patient required target vessel revascularization. The overall limb salvage rate during follow-up was 94.6%. One patient died of a myocardial infarction unrelated to the procedure 3 weeks after discharge.

Table 2. Comparison of baseline characteristics between the optimal and acceptable groups

Characteristic	Optimal group (n = 34)	Acceptable group (n = 6)	*P* value
Age, years	63.9 ± 11.3	64 ± 11.5	0.991
Gender, male	25 (73.5%)	5 (83.3%)	1.000
Hypertension	23 (67.6%)	4 (66.7%)	1.000
Diabetes mellitus	29 (85.3%)	6 (100%)	1.000
Chronic kidney disease	15 (44.1%)	3 (50%)	1.000
Dialysis	2 (5.9%)	2 (33.3%)	0.100
Coronary artery disease	15 (44.1%)	4 (66.7%)	0.398
Cerebrovascular ischemic event	1 (2.9%)	1 (16.7%)	0.281
Dyslipidemia	15 (44.1%)	4 (66.7%)	0.398
Smoking, pack × years	20 (0–50)	10 (0–36)	0.532
Current smoker	4 (11.8%)	2 (33.3%)	0.215
Chronic total occlusion	23 (63.9%)	4 (57.1%)	1.000
Lesion length, mm	270 (51–335)	290 (85–322)	0.964
TASC C–D lesions	33 (91.7%)	6 (85.7%)	0.523
PACSS 3–4 lesions	23 (63.9%)	6 (100%)	0.082

Data are presented as mean ± standard deviation, median (range), or number (percentage). TASC, Trans-Atlantic Inter-Society Consensus; PACSS, peripheral artery calcification scoring system.

Table 3. Comparison of resting Pd/Pa and cRR measurements after balloon angioplasty between the study group and the healthy tibial arteries group

	Study group (n = 40)	Healthy tibial arteries group (n = 14)	*P* value
ATA			
Resting Pd/Pa	0.92 ± 0.04 (n = 26)	0.93 ± 0.04 (n = 12)	0.429
cRR	0.90 ± 0.06 (n = 26)	0.93 ± 0.04 (n = 12)	0.130
PTA			
Resting Pd/Pa	0.94 ± 0.04 (n = 17)	0.95 ± 0.06 (n = 6)	0.828
cRR	0.92 ± 0.05 (n = 17)	0.92 ± 0.03 (n = 6)	0.834
Total			
Resting Pd/Pa	0.93 ± 0.04 (n = 43)	0.94 ± 0.05 (n = 18)	0.524
cRR	0.90 ± 0.06 (n = 43)	0.93 ± 0.03 (n = 18)	0.165

Data are presented as mean ± standard deviation. ATA, anterior tibial artery; Pd/Pa, distal pressure/aortic pressure; PTA, posterior tibial artery; cRR, constant-resistance ratio.

Discussion

The assessment of procedural success following balloon angioplasty for BTK artery lesions is critical for evaluating clinical outcomes. The present study population primarily consisted of patients with CLTI, more than 60% of whom had chronic total occlusions. Over 90% were classified as Trans-Atlantic Inter-Society Consensus C–D, and approximately 70% had peripheral artery calcification scoring system 3–4 complex BTK artery lesions. The majority presented with foot ulcers. Baseline characteristics were comparable between the optimal and acceptable groups. During short-term follow-up, high rates of wound healing, patency, and limb salvage were observed. Efforts were made to achieve optimal resting Pd/Pa and cRR values through balloon angioplasty using high inflation pressures and larger balloon diameters when necessary. The findings suggest that optimizing physiological indices–which enable hemodynamic functional assessment–may contribute to improved wound healing and clinical outcomes.

Physiological index measurements serve as quantitative parameters that eliminate inconsistencies often associated with the visual assessment of angiography in evaluating vessel patency and stenosis.[10] In the TARGET-FFR study, a final FFR value of ≤0.8 was considered indicative of an inadequate procedure, whereas a value ≥0.9 signified an optimal outcome in coronary artery disease.[11] Similarly, in a study on coronary artery lesions, Li et al.[7] reported a cRR threshold of 0.89 as indicative of physiologically relevant stenosis. Lei et al.[12] demonstrated a considerable correlation between resting Pd/Pa and gold-standard FFR measurements in coronary artery evaluations. Another coronary artery study found that resting Pd/Pa independently predicted long-term clinical outcomes.[13] Although standard cut-off values have not yet been established for PAD, the present study adopted cut-off values derived from coronary literature to define optimal and acceptable outcomes.

Adenosine, which induces maximal hyperemia and allows for optimal pressure measurements, is considered the gold standard for FFR assessment. However, it may cause side effects such as bradycardia and hypotension, and it can prolong procedure time.[14] In this study, resting pressure measurements were preferred as they provided effective and appropriate assessments while

avoiding potential side effects and procedural delays.

Recent studies have begun to explore FFR measurements in PAD. However, due to the limited number of studies, no standardization or consensus has yet been established regarding hemodynamic physiological assessment in PAD.[15] Kobayashi et al.[16] used FFR to grade residual dissections following balloon angioplasty in the superficial femoral artery, identifying patients who did not require bailout stenting. In a study on the iliac and superficial femoral arteries, FFR values were shown to strongly correlate with calf oxygenation, with high FFR values associated with successful revascularization.[8] Ruzsa et al.[9] reported that high final FFR values in BTK arteries were associated with freedom from re-intervention, major amputation, and mortality. In the present study, the principle of achieving better outcomes with high Pd/Pa and cRR values was adopted, and procedural success was determined based on physiological indices.

In BTK artery angioplasties, approaches involving oversized balloon use–up to 4 mm based on angiographic assessment–and gradual balloon diameter escalation up to 3.5 mm under IVUS guidance have yielded effective outcomes.[3,17] In a vascular reference diameter study conducted in older men, similar to the present study population, tibial artery diameters were reported as 3.8–4.2 mm.[18] In this study, optimal vessel patency in BTK arteries was evaluated using final physiological index measurements. Balloon inflation pressure and diameter were increased until the optimal threshold was achieved. In all patients without small body habitus, direct angioplasty with a 3.5 mm balloon was performed, achieving physiological values comparable to those in healthy tibial arteries for both the anterior and PTAs, without any vascular complications.

Following BTK angioplasty, complete wound healing within 3–4 months has been reported in approximately 60% of cases.[4,19] In the present study, nearly 70% complete wound healing was observed by the mean 3-month follow-up, suggesting that high wound healing rates may reflect the effectiveness of physiological vessel patency assessment. A meta-analysis of BTK lesions reported a 1-year major amputation rate of 5.5% and a 1-year primary patency rate of 50.6% in the balloon angioplasty group.[20] In the present study, despite the majority of lesions being anatomically complex and severely calcified, no target vessel revascularization was required during the short-term (mean 3-month) follow-up after achieving optimal resting Pd/Pa and cRR values.

Despite successful revascularization of large vessels, the presence of residual microvascular disease is known to increase the risk of amputation.[21] In two patients, major amputation was required due to worsening wound progression before the first follow-up examination, which may indicate that revascularization alone was insufficient for wound healing. During follow-up, mortality occurred in only one patient, who suffered a myocardial infarction after discharge, unrelated to the procedure.

In coronary artery disease, microcatheter-derived FFR measurements have been associated with better post-procedural outcomes than conventional angiography. Given the need for repeated pullbacks, microcatheter-based pressure measurements are considered safer than wire-based systems.[22] Unlike other PAD studies, in this study, measurements were performed using a pressure microcatheter advanced over the existing guidewire rather than a pressure wire.[8,9] In nearly half of the study population, the initial assessment was conducted using CO_2 angiography, followed by pressure measurements for procedural success determination and pedal arch imaging with iodinated contrast material. In BTK artery endovascular interventions, iodinated contrast volumes exceeding 100 mL may be required.[4] IVUS-guided anatomical imaging has enabled a near-zero contrast approach in BTK artery balloon angioplasties.[3] The present study demonstrated that pressure measurements contributed to a reduction in iodinated contrast material usage as a secondary outcome.

This study had several limitations. As a single-center, retrospective study, the follow-up period was relatively short. Wound, ischemia, foot infection classification, and body mass index were not included due to incomplete documentation in the retrospective records, which may limit the assessment of wound severity and nutritional status. The identification of constant-resistance periods used in the calculation of cRR is based on hemodynamic assumptions that have not yet been specifically validated in tibial arteries, potentially limiting its physiological applicability in this vascular territory. Because only patients with Rutherford category 4–6 were included, and lower categories were excluded, selection bias was unavoidable. Vasodilator agents were not used to avoid potential side effects; however, future studies incorporating FFR measurements with vasodilator agents may yield more definitive results.

Among the strengths of this study are the inclusion of healthy tibial arteries as a reference group, the determination of normal physiological values, and the objective evaluation of procedural success through classification based on physiological indices. Future multicenter, prospective, randomized controlled trials with long-term follow-up will be essential to further validate these findings. To the best of our knowledge, this is the first study to physiologically evaluate the efficacy and follow-up clinical outcomes of endovascular treatment in BTK arteries using resting Pd/Pa and cRR measurements.

In conclusion, high rates of wound healing and clinical improvement were observed in the optimal group. These findings suggest that high physiological index values may be associated with favorable clinical outcomes, although additional studies are necessary to confirm this association. Resting Pd/Pa and cRR may serve as objective parameters for evaluating the outcomes of endovascular treatment in BTK arteries.

Footnotes

Conflict of interest disclosure

The authors declared no conflicts of interest.

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