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ORIGINAL ARTICLE

GLASS of the foot: is the pedal arch modifier a useful tool or a confounding factor?

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ABSTRACT

INTRODUCTION: The Global Limb Anatomic Staging System (GLASS) has become a widely adopted tool for guiding treatment planning and prediction of revascularization success in chronic limb-threatening ischemia (CLTI). However, the proposed pedal modifier was not included in the initial validation studies, and information on its value as an adjunct to the classification remains scarce.

Our aim was to evaluate the pedal modifier as a predictor for wound healing and major adverse limb events (MALE) after primary endovascular CLTI revascularization.

METHODS: We conducted a retrospective analysis of patients who underwent their first endovascular revascularization for CLTI at a tertiary center between 2020 and 2021. Patients with no available diagnostic angiography were excluded. Electronic medical records were reviewed, and angiographic imaging was used to classify each procedure according to its GLASS score, including the pedal modifier. Adverse limb events were documented at 30 days, 3, 6, and 12 months.

RESULTS: A total of 118 patients were included in the study. Most patients (83.1%) presented with Rutherford 5 chronic limb ischemia, with GLASS severity scores evenly distributed (I 15.3%, II 40.7%, III 43.2%). Concerning pedal arch anatomy, 91.5% had at least one artery crossing the ankle to the foot with varying degrees of arch disease burden. A fully intact arch with minimal disease (P0) was observed in 32.2% of cases, while 53.4% had a diseased or absent arch (P1). Only 14.4% of patients had no named artery crossing the ankle (P2). The median follow-up was 12 months (IQR 6) with a MALE incidence of 34.9% (9.3% major amputation, 33.9% reintervention due to primary revascularization failure). Fifty-seven percent (61%) of patients achieved adequate wound healing during follow-up.

After stratification by the pedal modifier, the three groups (P0, P1, and P2) were comparable with respect to demographic and clinical variables. The outcome-related variables did not show any significant difference, either isolated or on a sub-analysis, after grouping for pedal GLASS severity.

DISCUSSION: Despite growing recognition of the role of anatomic disease burden in CLTI management, the predictive value of the GLASS pedal modifier remains unclear. Our findings suggest that pedal arch patency may not significantly influence revascularization success or amputation-free survival, and confirmation of our results in large multicenter data studies could lead to a paradigm shift.

Keywords: Chronic limb-threatening ischemia; Global limb anatomic staging system; Pedal arch; Inframalleolar disease

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INTRODUCTION

Chronic limb-threatening ischemia (CLTI), the end-stage of peripheral arterial disease, is defined by ischemic rest pain, tissue loss, or both, accompanied by objective hemodynamic impairment.[1] Management of such patients is complex and demands integrated medical and surgical treatment and thorough, prolonged follow-up. One of the biggest challenges is durable wound healing, which is a determinant of patients' quality of life, symptom relief, freedom from frequent (daily/weekly) visits to the outpatient clinic, and restoration of patients' independence. Most published papers fail to document and analyze this exact outcome variable, using amputation-free survival as a surrogate, and overlooking the lack of physical, social, and mental well-being attributed to having an active wound.[2,3] There is still much to clarify concerning treatment options, techniques, and prognostic factors, further complicated by the diffuse and heterogeneous patterns of disease, which pose a challenge for research development.

The Global Limb Anatomic Staging System (GLASS) was designed to standardize the anatomical classification and documentation of infrainguinal disease patterns and is now widely used as a guide for prediction of endovascular revascularization success and treatment planning in CLTI.[1] It classifies disease severity from least to most severe (I to III) based on high-resolution angiogram interpretation of femoropopliteal and infrapopliteal disease.

A pedal modifier (P0-2) representing the integrity of inframalleolar circulation was proposed as an adjunct for GLASS. However, due to lack of available evidence on its prognostic value, it was not included in the classification. After publication of the Global Vascular Guidelines (GVG) there has been a scarcity of data collection and publication on this topic, with some retrospective studies suggesting an association between pedal score, wound healing and amputation rate, as well as overall mortality.[4,5]

Our primary goal with this study is to evaluate the pedal modifier as a prognostic factor for endovascular revascularization outcomes of CLTI.

METHODS

Sample selection and data collection

This is a retrospective, single center study conducted at a tertiary hospital. The procedure registry between January 1st, 2020, and December 31st, 2021, was reviewed. All patients who underwent infrainguinal endovascular revascularization (EVR) for CLTI were included in the study, irrespective of treatment success. Exclusion criteria were purely diagnostic angiographies without a treatment attempt, previous ipsilateral infrainguinal limb revascularization, revascularization of the common or deep femoral arteries, and unavailability of angiographic imaging of the ankle and foot. A minimum follow-up of 30 days was required, and patients without a 30-day post-operative evaluation were excluded. All patients with nonatherosclerotic chronic vascular conditions were excluded.

Electronic medical records were retrospectively reviewed to collect data. Baseline demographic characteristics and comorbidities (present or past smoking habits, hypertension, dyslipidemia, diabetes mellitus [DM], chronic kidney disease [CKD], renal replacement therapy [RRT], coronary artery disease [CAD], congestive heart failure [CHF], and cerebrovascular disease [CVD]) were documented. The Rutherford classification for chronic limb ischemia [6] was used to categorize patients according to clinical severity. Information concerning endovascular revascularization was extracted from procedural reports and divided by intervention sector (femoropopliteal vs. infra-popliteal) and morphological and technique categories (stenosis treatment versus chronic total occlusion [CTO] recanalization; balloon angioplasty, stenting, or any other additional technique).

Angiographic imaging of each patient was analyzed, and disease anatomy was classified according to GLASS by segment, including infra-malleolar disease, and subsequently GLASS severity. As recommended, the target artery path (TAP) was defined as the angiosome-preferred or least diseased pathway to the foot. Treatment success was determined on completion angiography as restoration of direct flow to the foot and absence of persistent angiographically significant stenosis or dissection. Tibial vessel runoff ranged from 0 to 3, according to the number of infra-popliteal arteries crossing to the foot.

To ensure reviewer blindness to clinical outcomes, clinical data collection and angiographic GLASS classification were performed independently and stored in separate databases, linked only by a coded identifier to enable subsequent analysis.

Follow-up and outcome definitions

The primary outcome was wound healing (WiFI score W=0; I=any; FI=0). Secondary outcomes were ipsilateral major amputation, target arterial segment reintervention, and the composite outcome of major adverse limb events (MALE).[2] 30-day, 3-, 6-, and 12-month outpatient clinic records were reviewed for disease evolution and endpoint assessment. Follow-up was considered complete at 12 months or before in case of major amputation of the index limb.

Statistical analysis

Descriptive statistics were used to summarize patient characteristics, with continuous variables presented as mean and standard deviation (SD) when normally distributed, or median and interquartile range (IQR) when normality could not be assumed. Categorical variables were presented as absolute frequencies and percentages. Comparative analyses for continuous variables were conducted using t-tests and one-way ANOVA for normally distributed variables or, otherwise, using Mann-Whitney U and Kruskal-Wallis tests.

Chi-square tests were applied to analyze categorical variables. A multivariate regression analysis was performed to identify factors independently associated with the primary outcome. Independent variables were selected a priori based on clinical relevance and prior literature: DM, CKD, RRT, IP GLASS, and GLASS severity.

Time-to-event (healing and MALE) analyses were performed using Kaplan-Meier survival curves and a Cox proportional hazards regression to estimate hazard ratios (HRs) and 95% confidence intervals (CIs). Since sample size determination was not performed prior to protocol implementation, a post hoc power analysis was conducted. A p-value of <0.05 was considered statistically significant. Statistical analyses were conducted using IBM SPSS Statistics 30 (IBM Corp, Armonk, New York).

RESULTS

A total of 114 patients and 118 limbs were included in the analysis. Baseline characteristics of the sample are summarized in Table 1. The median age at the time of intervention was 72 years, and most patients (73.7%) were male. The most frequent comorbidities were diabetes mellitus (86.4%), dyslipidemia (85.6%), and hypertension (83.1%). Smoking habits, either present or past, were present in 35.6% of our sample. Patients had a range of cardiovascular conditions, including CAD in 40.7%, CHF in 28.8%, and CVD in 25.4%. Chronic kidney disease was a common comorbidity, representing 44.9% of our subjects, with 15.3% undergoing renal replacement therapy (RRT).

Most patients presented with Rutherford stage 5 (83.1%) or stage 6 (14.4%). Only three patients were treated for rest pain (Rutherford 4). Preprocedural GLASS status was categorized according to severity as 15.3% GLASS I, 49.7% GLASS II, 43.2% GLASS III, and pedal modifier as P0 in 32.2%, P1 53.4%, and P2 14.4%. Immediate treatment success was achieved in 95.8%, 15.3% with 3 runoff vessels, 39.8% with 2, and 36.4% with one, Table 2.

Outcome incidence is summarized in Table 3. The mean follow-up was 9.96 months (range: 1 to 12 months). Overall, 59.3% of patients achieved ulcer healing, but 34.4% presented with MALE during this period (33.9% due to reintervention and 9.3% major amputation).

Table 1. Baseline sample characteristics

	Total (n=118)	P0 (n=38)	P1 (n=63)	P2 (n=17)	p-value
Age, years median [IQR]	72 [15]	71 [16]	73 [13]	72 [16]	0.419
Sex, n (%)					
Male	87 (73.7)	28 (73.7)	45 (71.4)	14 (82.4)	0.682
Female	31 (26.3)	10 (26.3)	18 (28.6)	3 (17.6)	
Smoking, n (%)	42 (35.6)	17 (44.7)	17 (27.0)	8 (47.1)	0.123
Hypertension, n (%)	98 (83.1)	31 (81.6)	53 (84.1)	14 (82.4)	0.943
Dyslipidemia, n (%)	101 (85.6)	34 (89.5)	53 (84.1)	14 (82.4)	0.764
DM, n (%)	102 (86.4)	33 (86.8)	54 (85.7)	15 (88.2)	1.0
CKD, n (%)	53 (44.9)	19 (51.4)	27 (42.9)	7 (41.2)	0.711
Baseline creatinine, mg/dl	1.06 [0.64]	0.95 [0.54]	1.04 [0.67]	1.11 [0.94]	0.766
RRT, n (%)	18 (15.3)	6 (15.8)	10 (15.9)	2 (11.8)	0.943
CAD, n (%)	48 (40.7)	16 (45.7)	23 (36.5)	9 (52.9)	0.409
CHF, n (%)	34 (28.8)	10 (26.3)	20 (31.7)	4 (25.0)	0.811
CVD, n (%)	30 (25.4)	10 (26.3)	16 (25.4)	4 (23.5)	1.0
Rutherford classification, n (%)					
4	3 (2.5)	1 (2.6)	2 (3.2)	0	
5	98 (83.1)	30 (78.9)	54 (85.7)	14 (82.4)	0.86
6	17 (14.4)	7 (18.4)	7 (11.1)	3 (17.6)	

CAD: coronary artery disease; **CHF:** chronic heart failure; **CKD:** chronic kidney disease; **CVD:** cerebrovascular disease; **DM:** diabetes mellitus; **RRT:** renal replacement therapy; **IQR:** interquartile range

Table 2. Angiographic, anatomical and morphological characteristics.

	Total (n=118)	P0 (n=38)	P1 (n=63)	P2 (n=17)	p-value
Global Limb Anatomic Staging System (GLASS)					
Femoropopliteal grading, n (%)					
0	28 (23.7)	6 (16.2)	18 (28.6)	4 (23.5)	0.333
1	21 (17.8)	6 (16.2)	11 (17.5)	4 (23.5)	
2	24 (20.3)	11 (29.7)	9 (14.3)	4 (23.5)	
3	14 (11.9)	4 (10.8)	8 (12.7)	2 (11.8)	
4	30 (25.4)	10 (27.0)	17 (27.0)	3 (17.6)	
Infrapopliteal grading, n (%)					
0	18 (15.3)	5 (13.2)	11 (17.5)	2 (11.8)	0.531
1	18 (15.3)	7 (18.4)	9 (14.3)	2 (11.8)	
2	30 (25.4)	4 (10.5)	23 (36.5)	3 (17.6)	
3	29 (24.6)	10 (26.3)	12 (19.0)	7 (41.2)	
4	23 (19.5)	12 (31.6)	8 (12.7)	3 (17.6)	
Inframalleolar grading, n (%)					
0	38 (32.2)	-	-	-	-
1	63 (53.4)	-	-	-	-
2	17 (14.4)	.	.	.	.
Severity, n (%)					
I	18 (15.3)	4 (10.8)	13 (20.6)	1 (5.9)	0.148
II	48 (40.7)	12 (32.4)	26 (41.3)	10 (58.8)	
III	51 (43.2)	21 (56.8)	24 (38.1)	6 (35.3)	
Immediate treatment success, n (%)	113 (95.8)	36 (94.7)	60 (95.2)	17 (100.0)	0.509
Lesion type, n (%)					
Femoropopliteal segment					
Stenosis	86 (72.9)	31 (81.6)	42 (66.7)	13 (76.5)	0.245
CTO	36 (30.5)	11 (28.9)	19 (30.2)	6 (35.3)	0.923
Infrapopliteal segment					
Stenosis	90 (76.3)	24 (63.2)	53 (84.1)	13 (76.5)	0.058
CTO	56 (47.5)	17 (44.7)	29 (46.0)	10 (58.8)	0.644
Tibial run-off vessels after treatment, n (%)					
0	2 (1.7)	2 (5.6)	0	0	0.925
1	43 (36.4)	13 (36.1)	22 (38.6)	8 (47.1)	
2	47 (39.8)	16 (44.4)	24 (42.1)	7 (41.2)	
3	18 (15.3)	5 (13.9)	11 (19.3)	2 (11.8)	

CTO: chronic total occlusions

Table 3. Outcome presentation during follow-up

	Total	P0	P1	P2	p value
Wound healing, n (%)					
1-month	9 (7.6)	5 (13.2)	3 (4.9)	1 (5.9)	0.299
3-months	32 (27.1)	10 (32.3)	17 (29.3)	5 (33.3)	0.875
6- months	47 (39.8)	13 (48.1)	29 (51.8)	5 (41.7)	0.839
12-months	72 (61.0)	22 (57.9)	41 (65.1)	9 (52.9)	0.589
Reintervention, n (%)					
1-month	11 (9.3)	6 (15.8)	4 (6.3)	1 (5.9)	0.159
3-months	10 (8.5)	5 (16.1)	3 (5.0)	2 (13.3)	0.606
6- months	11 (9.3)	4 (14.8)	4 (6.9)	3 (25.0)	0.797
12-months	3 (2.5)	3 (12.0)	8 (14.5)	4 (33.3)	0.257
Cumulative	40 (33.9)	14 (36.8)	18 (28.6)	8 (47.1)	0.335
Major amputation, n (%)					
1-month	3 (2.5)	3 (7.9)	0	0	0.054
3-months	2 (1.7)	0	1 (1.7)	1 (6.7)	0.348
6- months	2 (1.7)	1 (3.7)	1 (1.7)	0	0.575
12-months	4 (3.4)	1 (4.0)	2 (3.7)	1 (8.3)	0.768
Cumulative	11 (9.3)	5 (13.2)	4 (6.3)	2 (11.8)	0.555
MALE at 12-months, n (%)	38 (34.9)	15 (40.5)	16 (28.6)	7 (43.8)	0.391

MALE: major adverse limb events

Pedal modifier subanalysis

No significant differences were noted in baseline characteristics of pedal modifier groups (P0, P1, and P2) (Table 1). DM was ubiquitous and showed no tendency towards a higher burden of pedal artery disease. CKD in general and RRT in particular were more frequent in P0 than in P2, although there was no statistically significant difference; also, a trend towards higher basal creatinine levels with increasing P class was identified.

Although no significant difference was found concerning femoropopliteal GLASS, both GLASS infrapopliteal score (p = 0.044) and severity (p = 0.045) were higher in P0 than the other groups. Treatment success did not differ between P groups. Wound healing at 12 months (57.9% vs. 65.1% vs. 52.9%, p = 0.535) as well as time-to-healing (p = 0.483) were similar between groups (Figure 1) and a cox regression analysis showed a hazard ratio (HZ) for ulcer healing of 0.823 (0.490-1.383, p = 0.462) for GLASS P1 and 0.804 (0.370-1.747; p = 0.582) for GLASS P2 vs. GLASS P0. MALE incidence (42.1% vs. 31.7% vs. 47.1%, p = 0.393) and MALE-free survival (p = 0.363; Figure 2) did also not show statistical difference (GLASS P1: HZ 1.243 [0.572-2.701]; p = 0.491; GLASS P2: HZ 1.023 [0.497-2.106]). Multivariate analysis was performed to investigate the impact of possible confounders (DM, CKD, RRT, tibial vessel run-off, GLASS IP score and overall severity) of GLASS P score effect on the primary outcome. However, the linear logistics regression model did not find any causal interference (Table 4).

Post-hoc power analysis

Given the negative results of this study, a post-hoc power analysis was conducted to ascertain its ability to detect difference between groups. The calculated power was 11.7%.

Figure 1. Cumulative Kaplane-Meier estimates wound healing after endovascular treatment in 118 patients chronic limb threatening ischemia stratified Global Limb Anatomic Staging System Pedal Modifier (GLASS-P). Wound healing rates at 12-months of GLASS-P0, 1 and 2 were, respectively, 57.9%, 65.1%, and 52.9% (p=0.483).

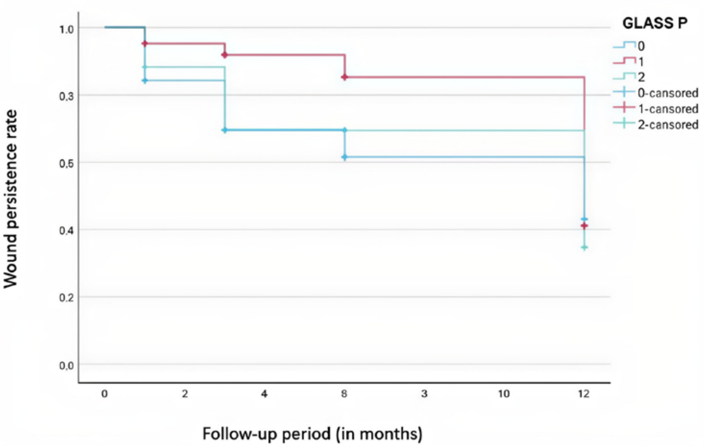

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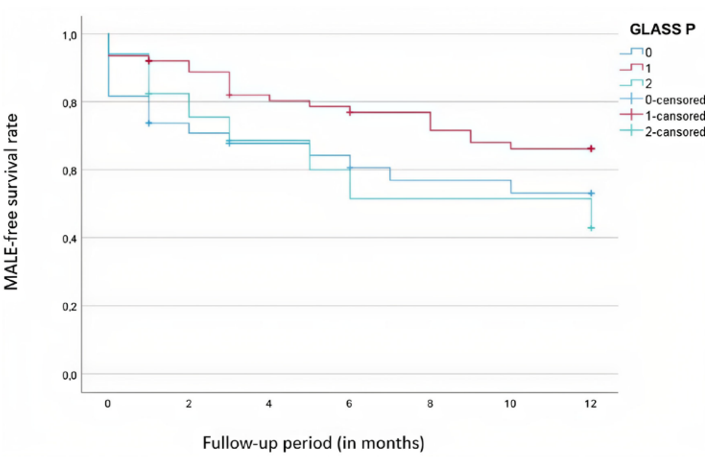
Figure 2. Cumulative Kaplan-Meier estimates for major limb adverse events (MALE) after endovascular treatment in 118 patients chronic limb threatening ischemia stratified Global Limb Anatomic Staging System Pedal Modifier (GLASS-P).



MALE-free survival rates at 12-months of GLASS-P0, 1 and 2 were, respectively, 40.5%, 28.6%, and 43.8% (p=0.391).

DISCUSSION

In our series of predominantly multilevel endovascular interventions for CLTI, GLASS-P did not predict our primary endpoint of wound healing at 12 months or our secondary endpoints of major amputation, reintervention, or MALE incidence, even after adjustment for potential confounders.

Miyake also found no correlation between GLASS-P and healing, although they introduced a new concept of perfusion-to-wound, which, rather than overall foot perfusion (as represented by GLASS-P), predicted healing of trophic lesions.[7]

On the other hand, recent publications contradict our findings.[4,8] Morisaki and Toyoshima found a correlation between non-healing ulcers and GLASS-P2, although the first author used a cohort of infra-popliteal EVT patients, excluding patients with femoropopliteal disease, which may overestimate the weight of pedal arch disease in a real-life setting, as most patients present with multi-sector disease. Overall, our healing and MALE rates at 12 months were consistent with the published literature.[4,8] Severe pedal arch disease (P2) varied widely between studies (4-43%), which may reflect both population variability and lack of grading reproducibility.[4,5,8,9] Surprisingly, DM and CKD were not associated with GLASS-P, a finding already described in literature, indicating that inframalleolar disease may not correlate with these risk factors as strongly as infrapopliteal disease.[8]

Finally, a relationship between GLASS-P0 and higher GLASS infrapopliteal scoring and GLASS severity was found. This is a novel association and may reflect the fact that higher complexity lesions in the supramalleolar segment (such as osteal occlusions and tibioperoneal trunk disease) do not directly correlate with diffuse and ultra-distal disease, although it highlights the fact that, considering this, infra-popliteal disease may be misrepresented using only the IP score.

Our study is not without limitations. Firstly, as a retrospective single-center study, our sample size may not be sufficient to detect a difference between groups, as indicated by the post hoc power analysis (11.7%). Replicating our protocol in a multicentric setting would overcome this limitation, allowing for more accurate and generalizable results. Secondly, since the angiographic imaging review was performed by the same team as the remainder of the data collection, there is a risk of measurement bias.

Table 4. Multivariable analysis of prognosis factor for wound healing

Variables	Univariate analysis		Multivariate analysis	
	OR (95% CI)	***p***	**OR (95% CI)**	***p***
DM	1.719 (0.592-4.986)	0.319		
CKD	0.507 (0.237-1.085)	0.080		
RRT	0.249 (0.085-0.728)	0.011	0.295 (0.096-0.905)	**0.033**
Tibial vessel run-off	1.032 (0.615-1.732)	0.904		
GLASS IP score				
1	2.262 (0.522-9.799)	0.275		
2	1.455 (0.422-5.009)	0.552		
3	0.717 (0.214-2.403)	0.590		
4	0.604 (0.169-2.157)	0.438		
GLASS severity				
2	0.430 (0.107-1.727)	0.234	0.485 (0.118-1.994)	0.316
3	0.198 (0.050-0.780)	**0.021**	0.223 (0.056-0.896)	**0.033**

CKD: chronic kidney disease; **DM:** diabetes mellitus; **IP:** infrapopliteal; **RRT:** renal replacement therapy

To avoid this, medical report review was staged with demographic, clinical, and outcome data collected after angiographic imaging classification. Consequently, investigators were blind to patient outcomes when applying the GLASS classification. Although the classification is fairly reproducible when applied by trained physicians, interobserver variability in GLASS classification may also contribute to grouping errors. Third, reporting of ulcer healing was not systematic because patients were evaluated by different physicians with distinct follow-up protocols. A structured follow-up protocol, such as image-based or WiFI score monitoring, could be more insightful both on the effect of revascularization according to GLASS stage but also enlighten us on possible confounding or contributing factors, since WiFI score seems to be correlated with disease healing as well.[4,8]

CONCLUSION

Our findings suggest that pedal arch patency may not significantly influence wound healing and major adverse limb events, and confirmation of our results in large multicenter studies could lead to a paradigm shift.

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