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Prospective Comparative Evaluation of Wagner, PEDIS, and Texas Classification Systems in Predicting Outcomes of Diabetic Foot Ulcers

Diyabetik Ayak Ülserlerinin Sonuçlarını Tahmin Etmede Wagner, PEDIS ve Texas Sınıflandırma Sistemlerinin Prospektif Karşılaştırmalı Değerlendirmesi

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Prospective Comparative Evaluation of Wagner, PEDIS, and Texas Classification Systems in Predicting Outcomes of Diabetic Foot Ulcers

ABSTRACT

Objective: This study aims to compare the effectiveness of three classification systems—Wagner, PEDIS, and Texas—in predicting treatment outcomes and amputation risk in patients with diabetic foot ulcers (DFUs). Given the high morbidity and mortality associated with DFUs, accurate prognostic tools are essential for guiding management and reducing limb loss.

Material and Method: A total of 121 patients diagnosed with DFUs between 2018 and 2020 at Hitit University Faculty of Medicine were enrolled in a prospective observational cohort study. Data collected included demographics, wound characteristics, ankle-brachial index (ABI), radiological findings, neuropathy status, and laboratory results. Patients were classified according to Wagner, PEDIS, and Texas systems. The relationship between classification results and clinical outcomes, such as healing and amputation, was analyzed using statistical methods, with significance set at $p<0.05$.

Results: The PEDIS system with a cutoff value of 7.5 effectively distinguished between healing and amputation cases. Wagner grade 4 and above significantly predicted higher amputation risk (AUC=0.728; $p<0.001$). Patients with ABI <0.9 showed a 50.9% amputation rate, compared to 23.5% in those with ABI ≥0.9. The neutrophil-to-lymphocyte ratio correlated with infection and higher amputation risk. Male gender, advanced age, and elevated neutrophil-to-lymphocyte ratios increased the likelihood of limb loss.

Conclusion: While PEDIS was more effective in differentiating healing from amputation, Wagner better predicted amputation risk. A lower ABI and high neutrophil-to-lymphocyte ratio were associated with worse outcomes. The study highlights the need for a comprehensive, universally applicable classification system that incorporates clinical and laboratory parameters to optimize patient management and reduce amputations.

Keywords: Amputation, Classification, Diabetic Foot Ulcer.

ÖZET

Amaç: Bu çalışma, diyabetik ayak ülseri (DAÜ) hastalarında tedavi sonuçlarını ve ampütasyon riskini öngörmede Wagner, PEDIS ve Texas sistemlerinin etkinliğini karşılaştırmayı amaçlamaktadır. DAÜ ile ilişkili yüksek morbidite ve mortalitenin göz önüne alındığında, doğru prognostik araçlar yönetimi yönlendirmek ve uzuv kaybını azaltmak için hayati öneme sahiptir.

Materyal ve Yöntem: 2018-2020 yılları arasında Hitit Üniversitesi Tıp Fakültesi'nde DAÜ tanısı konmuş toplam 121 hasta prospektif gözlemsel kohort çalışması olarak dahil edildi. Toplanan veriler arasında demografik bilgiler, yara özellikleri, ayak bilek-brakiyal indeks (ABI), radyolojik bulgular, nöropati durumu ve laboratuvar sonuçları bulunuyordu. Hastalar Wagner, PEDIS ve Texas sistemlerine göre sınıflandırıldı. Sınıflandırma sonuçları ile iyileşme ve ampütasyon gibi klinik sonuçlar arasındaki ilişki istatistiksel yöntemlerle analiz edildi ve anlamlılık $p<0,05$ olarak kabul edildi.

Bulgular: PEDİS sistemi, 7.5 eşik değeriyle iyileşme ve ampütasyon durumlarını etkili şekilde ayırt etti. Wagner sınıf 4 ve üzeri, anlamlı şekilde daha yüksek ampütasyon riskini öngördü (AUC=0.728; $p<0.001$). ABI <0.9 olan hastalarda ampütasyon oranı %50,9 iken, ABI ≥0.9 olanlarda bu oran %23,5 olarak bulundu. Nötrofil-lenfosit oranı enfeksiyon ve daha yüksek ampütasyon riski ile ilişkiliydi. Erkek cinsiyet, ileri yaş ve yüksek nötrofil-lenfosit oranları, uzuv kaybı olasılığını artırdı.

Sonuç: PEDIS, iyileşme ile ampütasyon arasındaki ayrımı daha iyi yaparken, Wagner ampütasyon riskini daha iyi öngördü. Düşük ABI ve yüksek nötrofil-lenfosit oranı kötü sonuçlarla ilişkiliydi. Çalışma, klinik ve laboratuvar parametrelerini içeren, uluslararası geçerliliği olan kapsamlı bir sınıflandırma sistemine ihtiyaç olduğunu vurgulamaktadır; böylece hasta yönetimi optimize edilip amputasyon oranları azaltılabilir.

Anahtar Sözcükler: Amputasyon, Sınıflandırma, Diyabetik Ayak Ülseri.

Introduction

The prevalence of diabetic foot ulcers (DFUs) continues to rise worldwide (1). DFUs are complex, chronic wounds with significant long-term impacts on morbidity, mortality, and quality of life (2,3). Unlike other chronic wounds, their development and progression are often complicated by diabetes-related alterations, such as neuropathy and vascular disease, which impair neutrophil function, reduce tissue perfusion, and hinder protein synthesis, creating unique management challenges in clinical practice (2).

Epidemiological studies indicate that the prevalence of DFUs ranges from 4% to 27%, with marked differences among countries (4–6). In the United States, prevalence is reported to be 15–20%, and the risk of amputation is 15–46 times higher in diabetic patients compared with non-diabetic individuals (7). Among individuals with type 2 diabetes, 12–15% develop DFUs, and approximately 14–24% of these cases result in amputation (8,9). Globally, it is estimated that one lower extremity is amputated due to diabetes every 20–30 seconds (1,10). The lifetime risk of ulcer development in diabetic patients has been estimated to reach up to 25% (8,9).

With an effective care plan, up to 85% of amputations can be prevented (11). However, inadequate education, insufficient assessment, inappropriate treatment methods, delayed referral, and limited access to multidisciplinary foot care teams reduce the chances of achieving optimal outcomes (12,13). DFUs therefore represent a major public health concern due to their high morbidity and mortality rates, prolonged hospital stays, and significant healthcare costs.

Accurate and practical classification systems are critical in guiding prognosis, treatment decisions, and communication among clinicians. Several systems have been developed for this purpose, including Wagner, PEDIS, and the University of Texas (UT) classification systems (14,15). Each emphasizes different dimensions of ulcer pathology: Wagner focuses on depth and gangrene, UT incorporates infection and ischemia in a stage–grade format, and PEDIS provides a numeric severity score based on perfusion, extent, depth, infection, and sensation (16). Although these systems are widely used, there is currently no universally accepted standard, and comparative evidence on their predictive validity remains limited (14–16).

In addition to ulcer-specific classification, systemic markers such as the ankle–brachial index (ABI) and neutrophil-to-lymphocyte ratio (NLR) have been identified as potential prognostic indicators. ABI, a non-invasive measure of arterial perfusion, is frequently abnormal in patients with DFUs and has been linked to poor healing and higher amputation rates (17). Elevated NLR, a marker of systemic inflammation, has also emerged as a simple but powerful predictor of adverse outcomes in diabetic wounds (18).

This study, therefore, aims to compare the predictive performance of the Wagner, PEDIS, and Texas classification systems in hospitalized patients with DFUs. Our primary objective is to evaluate their ability to predict clinical outcomes, specifically wound healing versus amputation. As secondary aims, we assess the prognostic value of ABI and NLR in risk stratification and treatment guidance. By integrating prospective clinical data with robust statistical analysis, we aim to contribute to the development of a more comprehensive, multidimensional classification model that can optimize limb preservation in diabetic patients.

Material and Method

The study was initiated after obtaining approval from the Clinical Research Ethics Committee of Hitit University Faculty of Medicine (date: 08.01.2020, decision number: 189). The protocol and informed consent form were reviewed and approved by the Ethics Committee. This clinical investigation was conducted in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki. All patients included in the study were informed about the tests to be performed and the methods to be used. Written informed consent was obtained from each participant to allow for the administration of tests and physical examinations. Consent for publication was obtained from all patients prior to participation.

In this prospective, observational cohort study, participants aged between 18 and 85 years, who were being monitored at the Diabetic Foot Clinic of Hitit University Faculty of Medicine, were included. For every hospitalized patient, all parameters defined

in the Diabetic Foot Ulcer Assessment Form were documented and verified by a healthcare team actively involved in diabetic foot ulcer management. During hospitalization, the patient group was monitored, and the following information from the Diabetic Foot Assessment Form was evaluated. Based on this information, patient data flow was ensured and recorded. The collected data included the patients' full name, age, gender, and other demographic characteristics; type of diabetes mellitus (DM); history of alcohol, smoking, or substance use; comorbid conditions associated with diabetic foot ulcers (neuropathy, nephropathy, and retinopathy); level of education regarding DM and diabetic foot ulcers; adherence to diabetes treatment with insulin and/or oral antidiabetic medications; history of prior amputations, including the level and laterality, if applicable; history of revascularization procedures, specifying whether angioplasty, bypass, or reperfusion was performed; radiological findings, including the presence of osteomyelitis or soft tissue infection; ulcer type, location, and duration; classification of the ulcer according to the Wagner classification, University of Texas classification, and PEDIS scoring system; ankle-brachial index (ABI) value, if available at admission; estimated treatment duration and outcome; final treatment outcome; and categorization of whether healing was achieved with other treatment modalities or amputation. Laboratory data were also assessed, including blood glucose, HbA1c, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), blood urea nitrogen (BUN), urea, creatinine, total cholesterol, hemoglobin, white blood cell (WBC) count, and neutrophil-to-lymphocyte ratio.

Patients included in the study underwent daily foot dressing changes, during which wound cultures were collected after foot cleansing. Photographs of all wounds were taken at hospital admission and recorded in the computerized patient files. The wounds were categorized and documented according to the Wagner classification, the University of Texas classification, and the PEDIS scoring system. For blood glucose regulation, all patients were consulted with the endocrinology or internal medicine departments to ensure proper glycemic control. In cases of infection, the infectious diseases department was consulted for antibiotic therapy and clinical evaluation. For revascularization assessment, patients were evaluated by the cardiology department, and when necessary, interventional peripheral angiography was performed, followed by revascularization if deemed appropriate. In cases of vascular occlusion, patients were referred to the cardiovascular surgery department, where revascularization or additional treatment recommendations were implemented as needed. Consultations with other specialties were conducted when required, contributing to diagnosis and treatment. During standard clinical care, all appropriate treatments administered to patients were systematically recorded.

Ulcer classification was performed using three validated systems: Wagner, PEDIS, and the University of Texas (UT) classification. Each patient was independently assessed by two clinicians with a minimum of five years of experience in diabetic foot care. To reduce observer bias, both clinicians were blinded to the patients' clinical outcomes at the time of scoring. A standardized case evaluation form was used to ensure uniform data capture, including ulcer location, depth, presence of infection, perfusion status, and neuropathy. Classification scoring was completed within the first 24 hours of hospital admission and prior to any surgical or antimicrobial interventions. In cases of inter-rater disagreement, a third independent clinician reviewed the case, and the final classification was determined by consensus.

Patients with a confirmed clinical diagnosis of diabetic foot ulcer were included based on documented findings from physical examination and wound assessment by two independent clinicians. The study encompassed a patient population aged between 18 and 85 years. Patients with diabetic foot ulcers of any severity were included, regardless of age or gender. Strict measures were implemented to protect patient confidentiality, ensuring that access to personally identifiable information was restricted to authorized personnel, preventing unauthorized access. Patients who died during the study period or discontinued treatment by refusing further medical care were excluded. Furthermore, patients were not included if, upon admission and during the anamnesis process, they were identified as having autoimmune disorders, immunological diseases, oncological conditions, dementia, vasculitis,

or if they were deemed medically unfit to provide informed responses to health-related inquiries on the patient profile form.

The primary outcome measures were healing and amputation, both assessed at hospital discharge. Healing was defined as complete epithelialization of the ulcer without the need for surgical intervention, confirmed by clinical examination. Amputation was defined as any surgical removal of tissue performed during hospitalization due to persistent infection, ischemia, or failure to heal, and was categorized as minor (below the ankle) or major (above the ankle). These standardized definitions were applied consistently for all patients.

Statistical Analysis

Statistical analyses were conducted using the SPSS software package (version 22, SPSS Inc., Chicago, IL, USA). Descriptive statistics for continuous variables obtained through measurement were expressed as mean ± standard deviation or median ± interquartile range (IQR), depending on the data distribution. Categorical variables were presented as frequency (n) and percentage (%). The normality of data distribution was assessed via the Shapiro-Wilk test. For comparisons between two independent groups, Student's t-test was used for normally distributed variables, and the Mann-Whitney U test for non-normal distributions. Relationships between categorical variables were analyzed using the Chi-square test or Fisher's exact test, as appropriate. To evaluate whether PEDIS and Wagner scores could serve as diagnostic and prognostic markers for healing and amputation, receiver operating characteristic (ROC) analysis was performed. ROC curves were generated, and the area under the curve (AUC) with 95% confidence intervals (CIs) was calculated. The AUC was classified as follows: 0.9–1.0 (excellent), 0.8–0.9 (good), 0.7–0.8 (moderate), 0.6–0.7 (poor), and 0.5–0.6 (failed diagnostic performance). The optimal cut-off point for ROC analysis was determined using Youden's index (maximum sensitivity and specificity). Based on these cut-off points, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and positive likelihood ratios (+LR) were calculated to assess the discriminative power of the parameters used in diagnosing healing and amputation. To identify potential risk factors influencing healing and amputation, univariate and multivariate logistic regression analyses were performed. Parameters with $p<0.10$ in the univariate logistic regression analysis were incorporated into the multivariate model, with odds ratios (ORs) and confidence intervals calculated. For all fundamental statistical tests, a significance level of $p<0.05$ was considered statistically significant.

Results

In this prospective and observational study, a total of 121 participants aged between 18 and 85 years, diagnosed with diabetic foot ulcers at varying levels and without any gender discrimination, were included. When the demographic characteristics of these patients were evaluated, two groups were formed: the healed group, consisting of 78 patients (64.5%), and the amputation group, comprising 43 patients (35.5%).

Of the 121 patients, 94 (77.7%) were male and 27 (22.3%) were female. The mean age of the patients was 64.88 ± 11.66 years. The gender distribution between the study groups was statistically significant ($p=0.036$). The mean age of patients in the healed group was 62.51 ± 10.91, whereas the mean age in the amputation group was 69.16 ± 11.86, demonstrating a statistically significant difference between the groups ($p=0.002$). The comparison of demographic characteristics, clinical features, and blood parameters among the study groups is presented in Table I. Among the blood parameters, only lymphocyte count and neutrophil-to-lymphocyte ratio (NLR) values showed statistically significant differences between the groups ($p=0.027$ and $p=0.012$, respectively). Other blood parameters were similar between the groups ($p>0.05$).

A statistically significant relationship was found between the Texas-ABCD classification and the study groups ($p=0.008$). It was observed that as the letter grade increased, the rate of amputation also increased. However, no statistically significant relationship was found between the Texas-123 classification and the study groups ($p=0.593$). Overall, a statistically significant association was identified between the Texas classification system and the study groups ($p=0.047$, Table II).

Table I. Comparison of Demographic Characteristics and Blood Parameters of Patients According to Groups

Variables	Group	Healed (n=78)	Amputation (n=43)	All Patients (n=121)	*p-value*
Gender n(%)	Male	56 (59.6)	38 (40.4)	94 (77.7)	*0.036*[c]
	Female	22 (81.5)	5 (18.5)	27 (22.3)	
BMI n(%)	18.5–24.9 (Normal Weight)	19 (59.4)	13 (40.6)	32 (26.4)	*0.462*[d]
	25–29.9 (Overweight)	43 (68.3)	20 (31.7)	63 (52.1)	
	30–34.9 (Obese Class 1)	8 (50)	8 (50)	16 (13.2)	
	35–39.9 (Obese Class 2)	5 (71.4)	2 (28.6)	7 (5.8)	
	>40 (Obese Class 3)	3 (100)	0 (0)	3 (2.5)	
Side n(%)	Right	39 (60)	26 (40)	65 (53.7)	*0.269*[c]
	Left	39 (69.6)	17 (30.4)	56 (46.3)	
DM, n(%)	Tip 1	1 (33.3)	2 (66.7)	3 (2.5)	*0.287*[d]
	Tip 2	77 (65.3)	41 (34.7)	118 (97.5)	
HT, n(%)	Yok	31 (73.8)	11 (26.2)	42 (34.7)	*0.117*[c]
	Var	47 (59.5)	32 (40.5)	79 (65.3)	
Nephropathy, n(%)	Yok	59 (67.8)	28 (32.2)	87 (71.9)	*0.218*[c]
	Var	19 (55.9)	15 (44.1)	34 (28.1)	
Retinopathy, n(%)	Yok	68 (63)	40 (37)	108 (89.3)	*0.377*[d]
	Var	10 (76.9)	3 (23.1)	13 (10.7)	
Neuropathy, n(%)	Yok	19 (73.1)	7 (26.9)	26 (21.5)	*0.300*[c]
	Var	59 (62.1)	36 (37.9)	95 (78.5)	
Alcohol, n(%)	Yok	72 (65.5)	38 (34.5)	110 (90.9)	*0.518*[d]
	Var	6 (54.5)	5 (45.5)	11 (9.1)	
Smoking, n(%)	Yok	62 (66)	32 (34)	94 (77.7)	*0.522*[c]
	Var	16 (59.3)	11 (40.7)	27 (22.3)	
Drug abuse, n(%)	Yok	75 (64.1)	42 (35.9)	117 (96.7)	*1.000*[d]
	Var	3 (75)	1 (25)	4 (3.3)	
Age, Mean±SD		62.51±10.91	69.16±11.86	64.88±11.66	***0.002***[a]
DM duration, Median±IQR		12±9	13±9	12±9	*0.778*[b]
Ulcer duration, Median±IQR		75±58	85±70	75±55	*0.086*[b]
Fasting Blood Glucose, Median±IQR		191.5±140	169±128	185±131	*0.150*[b]
Creatinine, Median±IQR		1.1±0.7	1.1±0.9	1.1±0.6	*0.325*[b]
Urea, Median±IQR		50.5±35	56±43	51±39	*0.404*[b]
Total Cholesterol, Mean.±SD		156.68±36.9	144.4±32.5	152.3±35.7	*0.070*[a]
Albumin, Mean±SD		31.69±5.37	32±4.77	31.80±5.15	*0.755*[a]
HbA1C, Median±IQR		8.5±1.9	8±3	8.4±2.4	*0.267*[b]
C-reactive protein (CRP), Median±IQR		39.5±81.5	78.6±105.2	48.6±99.2	*0.183*[b]
ESR, Median±IQR		37.5±29	38±29	38±29	*0.828*[b]
Hemoglobin, Mean±SD		11.24±1.85	10.63±1.75	11.02±1.83	*0.082*[a]
White blood cell count, Median±IQR		9.67±4.58	11.03±5.11	10.08±4.67	*0.211*[b]
Neutrophil, Median±IQR		7.26±4.38	8.54±4.99	7.71±4.72	*0.096*[b]
Lymphocyte, Median±IQR		1.84±1.24	1.42±0.54	1.62±1.11	***0.027***[b]
Neutrophil/lymphocyte ratio Median±IQR		3.77±4.54	6.12±4.93	4.41±4.75	***0.012***[b]

BMI: body mass index, DM: diabetes mellitus, HT: hypertension, IQR: interquartile range

SD: standard deviation,ESR: erythrocyte sedimentation rate, [a] Student's t test with mean±SD, [b] Mann Whitney U test with Median±IQR, [c] Chi-square test, [d] Fisher's Exact test

Table II. Statistical Findings Regarding the Comparison of PEDIS, Wagner, and Texas Classification Distributions Among the Study Groups

PEDIS SCORE SYSTEM	Healed N (%)	Amputation N (%)	Total N (%)	*p-value*
Perfusion 0	25 (89.3%)	3 (10.7%)	28 (100%)	*0.002*[c]
Perfusion 1	38 (63.3%)	22 (36.7%)	60 (100%)	
Perfusion 2	15 (45.5%)	18 (54.5%)	33 (100%)	
Sensation 0	37 (77.1%)	11 (22.9%)	48 (100%)	***0.019***[c]
Sensation 1	41 (56.2%)	32 (43.8%)	73 (100%)	
Extension 0	1 (100.0%)	0 (0.0%)	1 (100%)	*0.862*[d]
Extension 1	2 (100.0%)	0 (0.0%)	2 (100%)	
Extension 2	25 (65.8%)	13 (34.2%)	38 (100%)	
Extension 3	50 (62.5%)	30 (37.5%)	80 (100%)	
Depth 0	1 (100.0%)	0 (0.0%)	1 (100%)	***0.001***[d]
Depth 1	30 (85.7%)	5 (14.3%)	35 (100%)	
Depth 2	34 (64.2%)	19 (35.8%)	53 (100%)	
Depth 3	13 (40.6%)	19 (59.4%)	32 (100%)	
Infection 0	6 (60.0%)	4 (40.0%)	10 (100%)	***0.006***[d]
Infection 1	38 (82.6%)	8 (17.4%)	46 (100%)	
Infection 2	32 (52.5%)	29 (47.5%)	61 (100%)	
Infection 3	2 (50.0%)	2 (50.0%)	4 (100%)	
WAGNER GRADE				
Grade 1	9 (81.8%)	2 (18.2%)	11 (100%)	***0.001***[d]
Grade 2	29 (87.9%)	4 (12.1%)	33 (100%)	
Grade 3	20 (64.5%)	11 (35.5%)	31 (100%)	
Grade 4	10 (50.0%)	10 (50.0%)	20 (100%)	
Grade 5	9 (42.9%)	12 (57.1%)	21 (100%)	
Grade 6	1 (20.0%)	4 (80.0%)	5 (100%)	
TEXAS CLASSIFICATION				
A0	1 (100.0%)	0 (0.0%)	1 (100.0%)	***0.047***[d]
A1	11 (91.7%)	1 (8.3%)	12 (100.0%)	
A2	4 (100.0%)	0 (0.0%)	4 (100.0%)	
A3	3 (60.0%)	2 (40.0%)	5 (100.0%)	
B0	1 (50.0%)	1 (50.0%)	2 (100.0%)	
B1	7 (100.0%)	0 (0.0%)	7 (100.0%)	
B2	11 (73.3%)	4 (26.7%)	15 (100.0%)	
B3	1 (100.0%)	0 (0.0%)	1 (100.0%)	
C1	2 (66.7%)	1 (33.3%)	3 (100.0%)	
C2	3 (33.3%)	6 (66.7%)	9 (100.0%)	
C3	9 (64.3%)	5 (35.7%)	14 (100.0%)	
D1	4 (36.4%)	7 (63.6%)	11 (100.0%)	
D2	12 (60.0%)	8 (40.0%)	20 (100.0%)	
D3	9 (52.9%)	8 (47.1%)	17 (100.0%)	
Total	**78 (64.5%)**	**43 (35.5%)**	**121 (100.0%)**	

a Student's t test with mean±SD, b Mann Whitney U test with Median±IQR, c Chi-square test, d Fisher's Exact test

A statistically significant relationship was found between perfusion within the PEDIS scoring system and the study groups (*p=0.002*). However, wound extent within the PEDIS scoring system did not show a statistically significant relationship with the study groups (*p=0.862*). A significant relationship was observed between wound depth and the study groups (*p=0.001*), as well as between infection status and the study groups (*p=0.006*). Additionally, sensory impairment was significantly associated with the study groups (*p=0.019*). The comparison of PEDIS scores between the groups is presented in Table II, where scores were significantly higher in the amputation group (*p<0.001*).

Table III. Sensitivity, Specificity, Positive-Negative Predictive Values, and Positive Likelihood Ratio (LR+) of PEDIS, Wagner, and ABI Parameters

	PEDIS	Wagner	ABI
Cut off value	≥7.5	≥3.5	≥0.9
Sensitivity	0.814 (0.661-0.911)	0.605 (0.445-0.746)	0.628 (0.467-0.766)
Specificity	0.564 (0.447-0.674)	0.744 (0.630-0.833)	0.667 (0.550-0.767)
PPV	0.507 (0.385-0.629)	0.565 (0.412-0.708)	0.509 (0.370-0.647)
NPV	0.846 (0.714-0.927)	0.773 (0.659-0.859)	0.765 (0.644-0.856)
LR+	1.87 (1.40-2.50)	2.36 (1.51-3.69)	1.88 (1.28-2.78)

PPV: positive predictive value, NPV: negative predictive value, LR+: positive likelihood ratio, ABI: ankle-brachial index

To assess whether PEDIS scores could serve as a prognostic marker for predicting healing or amputation outcomes, ROC (Receiver Operating Characteristic) curve analysis was performed. The results, including sensitivity, specificity, positive and negative predictive values, and positive likelihood ratio (LR+), are presented in Table III. The ROC analysis demonstrated that the PEDIS score was significant in distinguishing between healing and amputation outcomes (AUC = 0.722, 95% CI: 0.629–0.816, *p<0.001*). The predictive performance of the PEDIS score is detailed in Table III.

When evaluating the relationship between the Wagner classification and study groups, a statistically significant association was found (*p=0.001*). It was observed that as the Wagner grade increased, the amputation rate also increased. ROC analysis for the Wagner classification showed it was significant in distinguishing between healing and amputation outcomes (AUC = 0.728, 95% CI: 0.633–0.822, *p<0.001*). The ROC curves for both PEDIS and Wagner classifications are shown in Figure I.

The optimal cut-off value for the Wagner classification was determined as 3.5. At this threshold, the classification performance was sensitivity = 60.5% (44.5–74.6%) and specificity = 74.4% (63.0–83.3%)

(Table III).

Patients with an ankle-brachial index (ABI) below 0.9 had a significantly higher amputation rate compared to those with an ABI of 0.9 or higher (*p=0.002*). The amputation rate was 23.5% in patients with ABI ≥ 0.9 and 50.9% in those with ABI < 0.9. The classification performance of ABI for predicting outcomes was sensitivity = 62.8% (46.7–76.6%) and specificity = 66.7% (55.0–76.7%) (Table III).

The results of univariate and multivariate binary logistic regression analyses, performed to identify factors influencing healing and amputation, are shown in Table IV. In the univariate analysis, significant parameters at *p<0.1* included gender, ulcer duration, age, diabetic foot care education (DMFCE), history of amputation, ulcer type, radiological findings, hemoglobin level, lymphocyte count, ABI, and diabetes mellitus education.

Table IV. Results of Univariate and Multivariate Binary Logistic Regression Analysis

	Univariate		Multivariate	
Variables	***p-values***	**Odds ratio (CI 95%)**	***p-values***	**Odds ratio (CI 95%)**
Gender (reference: female)	*0.042*	2.986 (1.040-8.573)	*0.011*	8.278 (1.628-42.093)
Age	*0.004*	1.055 (1.018-1.095)	*0.031*	1.060 (1.006-1.118)
Radiology: Soft tissue infection	*0.265*	0.560 (0.202-1.554)	*0.946*	0.953 (0.235-3.865)
Radiology: Osteomyelitis	*0.579*	0.667 (0.159-2.787)	*0.318*	0.398 (0.065-2.426)
Radiology: Soft tissue infection + osteomyelitis	*0.020*	3.200 (1.199-8.538)	*0.045*	4.386 (1.035-18.588)
ABI (Reference: ≥0.9)	*0.002*	3.375 (1.552-7.342)	*0.003*	5.385 (1.744-16.621)
PEDIS Prediction (reference: <7.5)	*<0.001*	5.662 (2.327-13.773)	*0.021*	3.930 (1.228-12.580)
Diabetic Foot Care Education (Reference: Diabetes education)	*<0.001*	10.956 (4.484-26.768)	*<0.001*	8.532 (2.770-26.275)
Ulcer duration	*0.061*	1.008 (1.000-1.016)	not included	
Hemoglobin	*0.085*	0.830 (0.671-1.026)	not included	
Lymphocyte count	*0.056*	0.576 (0.327-1.015)	not included	
Nagelkerke R Square: 0.595				

ABI: ankle-brachial index

The multivariate model, which incorporated these parameters, revealed that at *p<0.05*, the following factors were significant: gender (reference: female; OR = 8.28), age (OR = 1.06), radiological findings (soft tissue infection + osteomyelitis; OR = 4.39), ABI (reference: ≥ 0.9; OR = 5.39), PEDIS outcome prediction (<7.5; OR = 3.93), and diabetic foot care education (reference: diabetes education; OR=8.53). These results are summarized in Table IV.

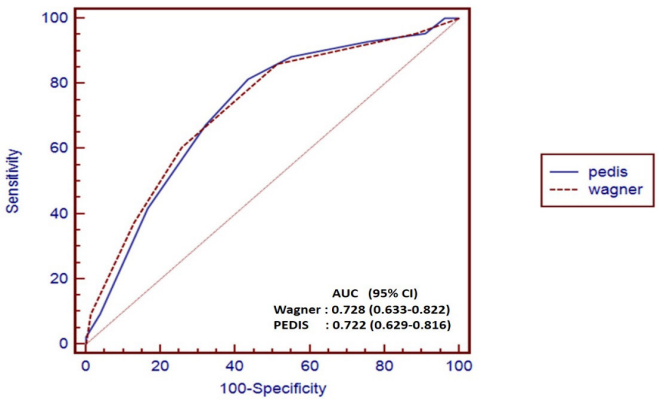

Figure I . ROC Curve Analysis for Outcome Prediction in the PEDIS and Wagner Classification Systems

Discussion

Diabetic foot ulcers (DFUs) have emerged as a significant public health problem in developing countries, paralleling the increasing prevalence of diabetes mellitus (DM). Resulting from neuropathy and/or peripheral vascular disease in an ischemic background, compounded by excessive pressure and infection, DFUs develop in approximately 15% of individuals with diabetes during their lifetime and require amputation in 7–20% of cases, representing a severe complication of diabetes (8). From a public health perspective, DFUs pose substantial concerns due to their high morbidity and mortality rates, prolonged hospital stays, and considerable healthcare costs. Therefore, early diagnosis and effective management are of critical importance for both patients and society. In this context, supportive tools for early detection and management, particularly classification and scoring systems—key prognostic assessment tools—play a crucial role in guiding clinical decision-making and improving patient outcomes. One of the widely utilized classification systems for DFU assessment is the Texas classification. It primarily grades ulcers based on depth and further

categorizes each grade using a staging system that differentiates between clean ulcers, infected ulcers, ischemic ulcers, and ulcers with both infection and ischemia (14,15). Due to its depth-based grading, the Texas system correlates well with the Wagner system in predicting major amputations and demonstrates superior performance in predicting wound healing compared to Wagner (14,15). Although it does not function as a scoring system, higher stages and grades are associated with worse clinical outcomes. Its complex practical application, however, remains a limitation.

In our study, both staging and grading within this classification were analyzed separately and in combination. We observed that as the stage (A, B, C, D) increased, the rate of amputation significantly rose between the groups. Conversely, when examining the grading (1-3) independently, no significant correlation was established. When evaluated together, a significant relationship was identified between the combined stage and grade and clinical outcomes. These findings support prior research indicating that the combined assessment of stage and grade offers prognostic value for healing and amputation. However, analyzing stage and grade separately did not yield the same predictive consistency. Thus, while the Texas classification demonstrates statistical significance in outcome prediction, it offers only moderate reliability.

An important aspect is the absence of neuropathy as a parameter within the Texas system, which is somewhat surprising. This omission is based on the premise that most patients with DFUs already have pre-existing neuropathy, rendering it a less useful differentiator once the ulcer has developed (14, 15). Our findings support this, as neuropathy evaluation did not significantly differ between groups. Although excluding neuropathy may be viewed as a limitation, the simplicity and clearly defined categories of the Texas system contribute to its widespread clinical use (15).

The PEDIS scoring system is another commonly employed classification tool. In this study, five parameters within PEDIS—perfusion, wound extent, wound depth, infection, and sensory function—were evaluated both individually and collectively. A significant relationship was found between perfusion status and clinical outcomes. Notably, the inclusion of ankle-brachial index (ABI) as a perfusion measure enhances the prognostic utility of PEDIS, as ABI values below 0.9 were significantly associated with higher amputation rates (*p=0.002*). This supports prior evidence that ABI is a valuable predictor of adverse outcomes in DFUs (17).

However, the wound extent parameter within PEDIS did not show a significant relationship with outcomes in our cohort, although other studies suggest that larger wound size correlates with poorer healing (16). Conversely, wound depth was significantly associated with outcomes, reinforcing the clinical relevance of this parameter. Sensory impairment also demonstrated a significant relationship, consistent with previous research highlighting its predictive importance. Infection severity, another critical component, was significantly linked to worse outcomes, aligning with literature indicating that increased infection severity prolongs hospitalization and raises amputation risk (19). Our ROC analysis confirmed that the PEDIS score is a significant prognostic marker, with a cut-off value of 7.5 providing moderate sensitivity and specificity.

The Meggitt-Wagner classification, characterized by its straightforward, six-grade structure, remains widely used due to its simplicity, despite limitations in data scope (10). In our study, most ulcers clustered around grades 2 and 3, consistent with prior findings. A significant association was found between Wagner grades and clinical outcomes (*p=0.001*), with higher grades correlating with increased amputation risk. The optimal cut-off was identified as 3.5, with moderate predictive accuracy—similar to previous studies (20,21). The consistency across literature supports the utility of Wagner grading in clinical practice, despite its limited scope.

Regarding vascular assessment, ABI proved to be a valuable predictor of amputation risk. Patients with ABI < 0.9 had significantly higher amputation rates, corroborating prior studies emphasizing ABI's sensitivity to lower extremity ischemia (17,22). Incorporating ABI into prognostic evaluation enhances predictive accuracy, underscoring its importance in comprehensive DFU assessment.

In summary, our findings indicate that the Texas, PEDIS, and Wagner classification systems hold varying degrees of prognostic value. The combined use of staging and scoring enhances predictive accuracy, while individual parameters such as perfusion and infection severity are crucial in outcome prediction. These tools, especially when used collectively, can guide clinicians toward more accurate prognosis and tailored management strategies, ultimately reducing morbidity and mortality associated with DFUs.

Conclusion

The PEDIS scoring system demonstrated the most significant capacity to distinguish between healing and amputation outcomes in diabetic foot ulcer (DFU) patients. Additionally, the Wagner classification effectively predicted the risk of amputation. The ankle-brachial index (ABI) also emerged as a crucial parameter in assessing amputation risk. Factors statistically significant in differentiating healing from amputation included male sex, advanced age, elevated neutrophil-to-lymphocyte ratio, absence of diabetic foot care education and general diabetes education, and the presence of soft tissue infection or osteomyelitis on radiological examination.

Current diabetic foot classification systems, despite their widespread use, are insufficient in guiding treatment and prognosis comprehensively. Notably, the Wagner classification, although easy to apply, lacks key prognostic factors such as neuropathy—an essential determinant of diabetic foot outcomes. Although neuropathy was not significantly associated with amputation risk in this study, the need for a new, comprehensive classification system is evident. Such a system should integrate clinically established prognostic factors, facilitate standardized treatment strategies, and be universally applicable across healthcare providers. Therefore, we advocate for the development and validation of a novel classification or scoring system that combines expert clinical experience with evidence-based prognostic factors, aiming to enhance treatment decision-making and improve patient outcomes.

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