Classification of diabetic foot disease using the WIfI system and related factors: a study at Cho Ray Hospital

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Abstract

Background: To describe the characteristics of Wound, Ischemia, and foot Infection (WIfI) classification in diabetic patients with foot complications. To analyze risk factors associated with WIfI clinical stages and 1-year clinical outcomes in this population.

Materials and Methods: A descriptive cross-sectional study conducted on 216 limbs in 208 patients with foot disease at Cho Ray Hospital from April 2023 to October 2023 and follow-up of 31 limbs in 30 patients up to October 2024.

Results: According to the WIfI classification, the distribution of limbs across clinical stages was 6.5% for Stage 1 (very low risk), 10.2% for Stage 2 (low risk), 19.9% for Stage 3 (moderate risk), and 63.4% for Stage 4 (high risk). Factors significantly associated with WIfI clinical stages included infection ($p< 0.001$), tissue loss ($p=0.006$), loss of protective sensation (LOPS) assessed by monofilament ($p=0.011$), tuning fork ($p=0.047$), and the Ipswich Touch Test (ITT) ($p=0.011$), triglycerides (TG) ($p=0.01$), hemoglobin (Hb) ($p=0.016$), LDL-C ($p=0.008$). Factors significantly associated with clinical outcomes included LOPS assessed by monofilament ($p = 0.018$), tuning fork ($p = 0.003$), and the Ipswich Touch Test ($p = 0.018$). Toe-Brachial Index (TBI) demonstrated a statistically significant predictive value at 1 year (AUC = 74.4%; $p = 0.021$).

Conclusions: The WIfI classification system should be considered for initial implementation in the assessment of diabetic foot disease in Vietnam. The TBI should be considered in the clinical assessment of the diabetic foot.

Keywords: WIfI; classification; diabetic foot.

1. BACKGROUND

Diabetes mellitus is a chronic condition that leads to numerous severe complications, imposing a tremendous burden on health and finances for patients, families, and society. Among these, diabetic foot disease (DFD) is a critical complication that prolongs hospital stays and increases medical costs. The prevalence of limb amputation in patients with DFD, according to both domestic and international studies, remains alarmingly high. According to Wukich (2013), this rate was 51% [1], while Richard (2011) reported 35% [2], and Huynh Tan Dat (2024) observed 46.5% [3]. Globally, a lower limb is amputated every 20 seconds due to diabetes [4].

Commonly used classification systems for assessing diabetic foot include PEDIS, Wagner, and the University of Texas system. While widely implemented in clinical practice, these systems have certain limitations. Specifically, diabetic foot presentations in Vietnamese patients often involve a complex combination of ulceration, ischemia, and infection. Therefore, a comprehensive tool is necessary to evaluate the diabetic foot more holistically. In Vietnam, research regarding the WIfI classification system for diabetic patients remains limited. Furthermore, there is a paucity of studies utilizing TP and TBI indices, and to the best of our knowledge, no research has yet tracked one-year clinical outcomes using these specific diagnostic tools.

In 2014, the Society for Vascular Surgery (SVS) introduced the WIfI classification (Wound, Ischemia, and foot Infection) [5]. This system is based on the severity of ischemia, wound extent/gangrene, and infection, and is utilized to predict the one-year risk of major limb amputation [5]. A systematic review by van Reijen (2019) showed that the amputation rates for WIfI clinical stages 1 through 4 were 8%, 11%, 38%, and 58%, respectively [6]. Furthermore, the WIfI system assists in predicting wound healing outcomes. Weaver (2018) demonstrated that the wound healing rate for WIfI stages 1/2 was significantly higher than for stages 3/4 (77.3% vs. 57.2%) [7].

To initially evaluate the distribution of diabetic foot phenotypes and factors associated with this classification system, we conducted this study with the following objectives: To describe the characteristics of WIfI classification in diabetic patients with foot disease and to analyze factors associated with WIfI stages and 1-year clinical outcomes in these patients.

2. SUBJECTS AND METHODS

2.1. Study design: The study consisted of two phases: an initial descriptive cross-sectional phase involving 216 limbs from 208 patients, followed by a one-year follow-up phase for a subset of 31 limbs in 30 patients.

2.2. Subjects:

Research subjects: Inpatients presenting with diabetic foot at Cho Ray Hospital between April 2023 and October 2023.

Sample size: 216 limbs in 208 patients at the descriptive cross-sectional phase and 31 limbs in 30 patients at the follow-up phase.

Sampling method: Consecutive sampling throughout the cross-sectional phase. During the follow-up phase, we contacted all reachable patients to determine clinical outcomes: no-amputation, amputation, or death.

Inclusion criteria: Diabetic foot diagnosed according to IWGDF 2019: Infection, ulceration, or destruction of tissues of the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of a person with (a history of) diabetes mellitus. For patients without a prior history of diabetes: Individuals will still be included if they fulfill the diagnostic criteria for diabetes mellitus as defined by the ADA 2023 guidelines [8].

Exclusion criteria: The study excluded patients who declined to provide informed consent or those presenting with foot ulcers of non-diabetic origin, such as those caused by gouty tophi, post-traumatic fractures, or rheumatoid arthritis. Cases in which key study parameters, such as ABI, TBI, TP, and foot classification, cannot be determined.

2.3. Data analysis:

Statistical analysis was performed using SPSS version 20.0 and Microsoft Excel. Univariate analysis of associated factors was conducted using Pearson's Chi-square test, with a significance level of $p < 0.05$. ROC curve analysis was used to evaluate the predictive value of TBI for the one-year outcome.

2.4. Key variables:

WIfI classification, Ankle-Brachial Index (ABI), Toe-Brachial Index (TBI), Toe Pressure (TP), and White Blood Cell (WBC) count were applied according to the 2014 SVS guidelines [5]. Glycemic and lipid profile targets, HbA1c and other laboratory parameters were based on the American Diabetes Association (ADA) Standards of Medical Care in Diabetes 2023 [8].

If both limbs met the diabetic foot criteria, both were recorded and assessed. Clinical examinations were performed on all limbs, with ankle and toe blood pressures measured using Lifedop and Systoe devices, respectively. ABI, TBI, and TP were calculated for all limbs. All measurements were obtained by the investigator and confirmed in the hospital medical records.

Calculation of ABI: For the leg being assessed, measure the systolic blood pressure in both the dorsalis pedis artery and the posterior tibial artery. Select the lower of these two values, then divide it by the highest systolic blood pressure measured in either the right or left arm.

Measurement of TP: Wrap the toe cuff around the base of the great toe. Secure the photoplethysmography (PPG) sensor—which includes the LED light—onto the tip of the toe. Initiate the measurement and wait for the results to be displayed on the screen.

Calculation of TBI: Divide the Toe Pressure (TP) value of the leg being assessed by the highest systolic blood pressure measured in either the right or left arm.

Ischemia (of WIfI classification): We use ABI, ankle pressure, and TP to assess ischemia according to the SVS guidelines. If TP and ABI measurements result in different grades, TP will be the primary determinant of ischemia grade [5].

Foot infection (of WIfI classification): We use the SVS adaptation of the Infectious Diseases Society of America (IDSA) and International Working Group on the Diabetic Foot (IWGDF) perfusion, extent/size, depth/tissue loss, infection, sensation (PEDIS) classifications of diabetic foot infection according to the SVS guidelines [5].

One-year clinical outcomes included: no-amputation, amputation or death. We contacted the patients or their family members either in person, or via phone or video calls. Patients who were reachable and consented to share their results were included in the outcome data collection. Those who could not be reached or declined contact were excluded from the follow-up cohort. Outcomes were assessed exactly one year following the initial examination.

2.5. Ethical considerations

The study was approved by the Institutional Ethics Committee of the University of Medicine and Pharmacy, Hue University, under Decision No. 1138/QD-DHYD, dated May 10, 2021.

3. RESULTS

3.1. General characteristics of the study population

3.1.1. Baseline characteristics

Table 1. Distribution of age and gender

Gender	N	Percentage (%)	Age (± SD)
Male	105	50.5	58.17 ± 10.39
Female	103	49.5	61.22 ± 12.18
Total	208	100.0	59.71 ± 11.40

The distribution of male and female patients was equivalent, at 49.5% and 50.5%, respectively. The overall mean age was 59.71 ± 11.403; the mean age for females was higher than for males 61.22 ± 12.18 years vs. 59.71 ± 11.40.

3.1.2. Clinical characteristics

Table 2. Clinical characteristics

Clinical characteristics	N	Percentage (%)
Hypertension history	117	54.2
Dyslipidemia history	45	20.8
Smoking history	54	25.0
Infection	206	95.4
Tissue loss	207	95.8
Charcot foot	38	17.6
Loss of protective sensation (LOPS)		
10-g Monofilament	111	51.4
128-Hz Tuning fork	120	55.6
Ipswich Touch Test	111	51.4
ABI < 0.9 or > 1.3	65	30.1
TBI < 0.7	195	90.3
TP < 60mmHg	136	63.0

Limbs with a history of hypertension accounted for a high proportion at 54.2%, followed by smoking at 25% and dyslipidemia at 20.8%. Most limbs with diabetic foot complications present with infected wounds and loss of tissue. Approximately half of the limbs exhibit symptoms of loss of protective sensation (LOPS). The prevalence of abnormal ABI, TP, and TBI was 30.1%, 63%, and 90.3%, respectively.

3.1.3. Laboratory characteristics

Table 3. Laboratory characteristics

Variable	Unit	N	Mean	Min – Max
HbA1c	%	197	10.16 ± 2.63	5.16-19.3
TC	mg/dL	201	135.84 ± 42.77	40 - 349
TG	mg/dL	203	174.22 ± 95.96	0 - 740
HDL	mg/dL	202	29.23 ± 12.27	6 - 75
LDL	mg/dL	210	74.186 ± 34.98	8.4 - 208
WBC	G/L	208	12.6102 ± 6.32	2.23 - 53.65

Hb	g/dL	208	10.24 ± 1.74	6.6 - 15.2
Urea	mg/dL	206	18.80 ± 21.60	4- 230
Creatinine	mg/dL	215	1.1109 ± 1.34	0.3 – 11.08

The laboratory indicators of the study subjects tend to deviate from the reference ranges of healthy individuals.

3.1.4. Clinical outcome after one year

Clinical outcome	N	Percentage (%)
No amputation	17	54.8
Amputation	9	29.1
Death	5	16.1
Total	31	100

Among 30 patients and 31 lower extremities followed for one year, the outcomes were 54.8% no-amputation limbs, 29.1% amputation, and 16.1% mortality

3.2. Characteristics of WIfI classification in diabetic patients with foot disease

3.2.1. WIfI classification components

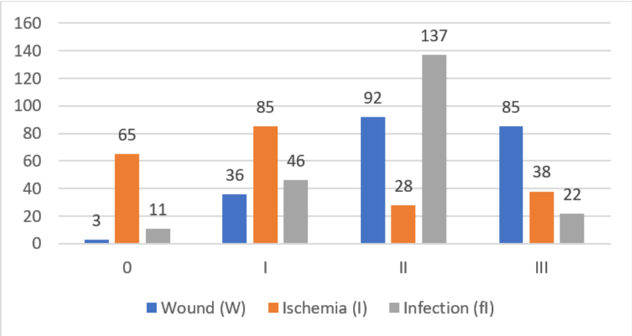

Figure 1. WIfI classification components

The Wound component was most prevalent at Grade II (n=92), followed by Grade III (n=85), and least prevalent at Grade 0 (n=3). The Ischemia component was most frequent at Grade I (n=85) and least frequent at Grade II (n=22). The foot Infection (fI) component was most prevalent at Grade II (n=92) and least frequent at Grade I (n=11). Overall, Grade II accounted for the highest cumulative number of components (n=257)

3.2.2. Clinical stages of WIfI classification

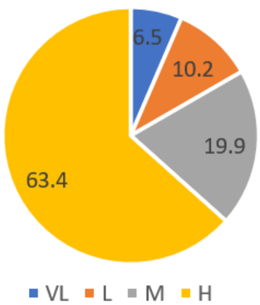

Figure 2. Distribution of clinical stages according to WIfI classification

Lims at high risk (Stage 4) accounted for the highest proportion at 63.4%, followed by moderate risk (Stage 3) at 19.9%, low risk (Stage 2) at 10.2%, and very low risk (Stage 1) at only 6.5%.

3.3. Association between risk factors and WIfI classification

3.3.1. Association between clinical characteristics and WIfI clinical stages

Table 3.5. Clinical characteristics of the study population by WIfI stages

Clinical characteristics		N	Stage 1	Stage 2	Stage 3	Stage 4	P
Hypertension	Yes	117	8	11	20	78	> 0.05
	No	99	6	11	23	59	
Dyslipidemia history	Yes	45	2	7	9	27	> 0.05
	No	171	12	15	34	110	
Smoking history	Yes	54	4	4	8	38	> 0.05
	No	162	10	18	35	99	
Infection	Yes	206	10	20	40	136	**< 0.001**
	No	10	4	2	3	1	
Tissue loss	Yes	207	11	21	40	135	**0.006**
	No	9	3	1	3	2	
LOPS with 10-g Monofilament	Yes	111	3	8	19	81	**0.011**
	No	105	11	14	24	56	
LOPS with 128-Hz Tuning fork	Yes	120	4	9	23	84	**0.047**
	No	96	10	13	20	53	
LOPS with Ipswich Touch Test	Yes	111	3	8	19	81	**0.011**
	No	105	11	14	24	56	
Charcot foot	Yes	38	1	1	7	29	> 0.05
	No	178	13	21	36	108	

There were statistically significant differences between WIfI stage with infection (p< 0.001), tissue loss (p=0.006), loss of protective sensation (LOPS) assessed by monofilament (p=0.011), tuning fork (p=0.047), and the Ipswich Touch Test (ITT) (p=0.011). There were no statistically significant differences between medical history and the other clinical characteristics (p > 0.05).

3.3.2. Association between laboratory characteristics and WIfI clinical stages

Table 6. Association between laboratory characteristics of the study population and WIfI stages

Laboratory characteristics		Stage 1	Stage 2	Stage 3	Stage 4	Total	p
HbA1c	< 7%	2	4	5	12	23	>0.05
	>=7%	12	17	36	117	182	
Total Cholesterol	>= 200mg/dl	1	4	3	6	14	>0.05
	< 200mg/dl	13	18	40	123	194	
TG	<150 mg/dL	4	6	18	76	104	**0.01**
	>=150 mg/dL	10	16	25	56	107	
HDL-C	<=40mg/dl (men) or <=50 mg/dL (women)	12	18	38	121	189	0.402
	>40mg/dl (men) or >50 mg/dL (women)	2	4	4	11	21	
LDL-C	<70 mg/dL	12	18	38	127	195	**0.008**
	>=70 mg/dL	2	4	5	4	15	

WBC	<4K or > 12K	4	5	21	65	95	>0.05
	4K-12K	10	17	22	72	121	
Hb	>=12g/dL	4	7	8	14	33	**0.016**
	<12g/dL	10	15	35	123	183	
Urea	>= 45mg/dL	0	0	0	10	10	0.166
	< 45mg/dL	14	22	42	126	204	
Creatinine	>= 1.47 mg/dL	0	0	5	19	24	0.141
	< 1.47 mg/dL	14	22	38	117	191	

There were statistically significant associations between TG, Hb, LDL-C and WIfI stages (p = 0.01, 0.016, and 0.008, respectively). No significant associations were found between other laboratory characteristics and WIfI stages.

3.4. Association between clinical characteristics and clinical outcomes

Table 7. Association between clinical characteristics and clinical outcomes

Clinical characteristics		N	Amputation and death	No-amputation	p
Hypertension	Yes	17	6	11	> 0.05
	No	14	8	6	
Dyslipidemia history	Yes	7	2	5	> 0.05
	No	24	12	12	
Smoking history	Yes	5	2	3	> 0.05
	No	26	12	14	
Infection	Yes	30	14	16	**1.0**
	No	1	0	1	
Tissue loss	Yes	31	14	17	**---**
	No	0	0	0	
LOPS with 10-g Monofilament	Yes	10	8	2	**0.018**
	No	21	6	15	
LOPS with 128-Hz Tuning fork	Yes	13	10	3	**0.003**
	No	18	4	14	
LOPS with Ipswich Touch Test	Yes	10	8	2	**0.018**
	No	21	6	15	
Charcot foot	Yes	1	1	0	> 0.05
	No	30	13	17	
ABI	0.9-1.3	21	10	11	1.0
	<0.9 or > 1.3	10	4	6	
TBI	< 0.7	26	13	13	0.344
	≥ 0.7	5	1	4	
TP	<60	19	11	8	0.073

Among the 31 limbs followed up, there were statistically significant associations between LOPS (10-g Monofilament, 128-Hz Tuning fork, and Ipswich Touch Test) and clinical outcomes (p = 0.018, 0.003, and 0.018, respectively). Conversely, no significant associations were found between medical history, other clinical symptoms, ABI, TBI, TP, and clinical outcomes.

3.5. Association between laboratory characteristics and clinical outcomes

Table 8. Association between laboratory characteristics and clinical outcomes

Laboratory characteristics		Amputation and death	No-amputation	Total	p
HbA1c	<7%	13	16	29	>0.05
	>=7%	0	1	1	
Total Cholesterol	>= 200mg/dl	0	3	0	> 0.05
	< 200mg/dl	14	12	26	
HDL-C	<=40mg/dl (men) or <=50 mg/dl (Women)	14	17	31	---
	>40mg/dl (men) or >50 mg/dl (women)	0	0	0	
LDL-C	<1.8mmol/ L	14	15	29	>0.05
	>=1.8mmol/L	0	2	2	
TG	<1.7mmol/L	5	6	11	>0.05
	>=1.7mmol/L	9	11	20	
WBC	WBC <4 or > 12k	8	5	13	>0.05
	Normal	6	12	18	
Hb	>=12g/dL	2	1	3	>0.05
	<12g/dL	12	16	28	
Ure	>= 7.5mmol/L	1	0	1	>0.05
	< 7.5mmol/L	13	17	30	
Creatinin	>= 130 µmol/l	2	0	2	>0.05
	< 130 µmol/l	12	17	29	

There was no association between laboratory characteristics and clinical outcomes.

3.6. Correlation between limb perfusion indices and clinical outcomes

Table 9. Correlation between limb perfusion indices and clinical outcomes

Indices	Cut-off	AUC (%)	Sensitivity (%)	Specificity (%)	p
ABI	1.08	0.574	0.353	0.714	0.487
TBI	0.47	0.744	0.647	0.786	**0.021**
TP	54.5	0.695	0.706	0.714	0.065

ROC analysis demonstrated that ABI had low predictive value and was not statistically significant at 1 year. Conversely, TBI reached statistical significance at 1 year (AUC = 74.4%; p = 0.021), with fair sensitivity and specificity. TP showed moderate predictive value at 1 year (AUC = 69.5%) but did not reach statistical significance (p > 0.05).

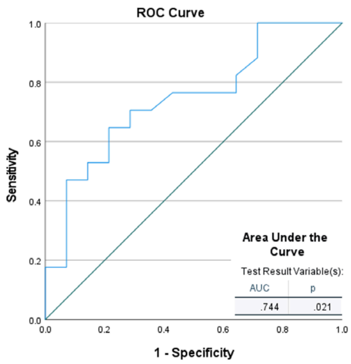

Figure 3. Correlation between TBI and clinical outcomes

TBI reached statistical significance at 1 year (AUC = 74.4%; p = 0.021), with fair sensitivity and specificity.

4. DISCUSSION

4.1. General characteristics of the study population

Among 208 patients with diabetic foot, the proportion of males was equivalent to females; however, the absolute number of males was slightly lower than females. This represents a minor difference compared to previous studies by Caitlin et al. (2017), which reported a male proportion of 60.3% [9], and Jeremy et al. (2015), where males accounted for 59% [10].

Regarding medical history, in addition to diabetes, the majority of limbs had comorbidities such as hypertension (54.2%) and dyslipidemia (20.8%). Compared to the studies of Luke (2015) [11], William (2016) [12], and Hicks (2017) [9], these are also the two most common comorbidities, with the prevalence of concurrent hypertension ranging from 82.9% to 86% and dyslipidemia ranging from 57% to 74%. Simultaneously, 25.0% of the study subjects were smokers, which is lower than the rates reported by William et al. (2016) at 68% [12], Jeremy (2015) at 61% [10], and Hicks (2017) at 54.5% [9].

Regarding medical history, hypertension is a significant factor, affecting more than half of the study population. Chronic hypertension in the setting of long-standing diabetes can promote atherosclerosis and impair distal perfusion. This, in turn, creates pressure gradients between the toe, ankle, and brachial levels, thereby exacerbating the severity of diabetic foot disease. Among the 31 limbs under follow-up, 9 underwent amputation, and 5 were associated with patient mortality. Among the limbs resulting in amputation and mortality, 11 were classified as WIfI stage 4, accounting for 78.6%. This suggests that a higher WIfI stage is associated with an increased risk of limb amputation and mortality in patients with diabetic foot. However, given the limited sample size, these preliminary findings warrant careful interpretation.

4.2. Characteristics of WIfI classification in diabetic patients with foot disease

The WIfI classification system is based on the individual assessment of three core components: Wound, Ischemia, and foot Infection. It utilizes a grading scale from 0 to 3, where 0 represents none, 1 indicates mild, 2 indicates moderate, and 3 indicates severe [5].

Each clinical case is evaluated based on its components, where each theoretical patient combination correlates with the risk of amputation (Stage 1 – very low; Stage 2 – low; Stage 3 – moderate; and Stage 4 – high). The clinical stage is shown to increase as one moves toward the right (indicating increasing severity of each individual WIfI component) [5].

Comparing the components with the WIfI clinical stage assessment table for patients in this study, stages 1, 2, 3, and 4—corresponding to Very Low (VL), Low (L), Moderate (M), and High (H) risk levels—accounted for 6.5%, 10.2%, 19.9%, and 63.4% respectively. The combined percentage for stages 3 and 4 reached 83.3%. This figure is notably higher than those reported in studies by Weaver et al. (70.67%) [7], Hicks (47.6%) [9], William P. Robinson et al. (53%) [12], and Luke X. Zhan (55.7%) [11]. This indicates that the majority of diabetic patients with foot disease face a high risk of amputation; these subjects require continuous monitoring and future prospective studies. However, in our study, a high proportion of patients were classified as stage 3-4, in Vietnam, individuals residing in tropical environments may not have received adequate clinical attention or regular diabetic foot screening. Patients typically present to hospitals for examination and treatment only when symptoms are clinically manifest and severe, which may contribute to the increased prevalence of stage 3-4 cases. Furthermore, this finding could be attributed to the fact that our study population consisted of inpatients, who generally exhibit more advanced disease stages compared to outpatients.

4.3. Association between WIfI stages and risk factors

Assessment of foot sensation using the 10-g Monofilament, 128-Hz tuning fork, and ITT revealed that the presence of loss of protective sensation (LOPS) was statistically significantly associated with different stages of diabetic foot disease (p=0.011, 0.047, and 0.011 respectively). In the study by Caitlin W. Hicks, LOPS (93.2%) was statistically significant with p < 0.01 [9]; however, in the study by William P. Robinson [12], this association was not statistically significant (p = 0.92). Furthermore, the presence of infection and tissue loss were statistically significantly associated with WIfI stages (p < 0.001 and p=0.006). The loss of protective sensation is a frequent finding in patients with diabetic foot disease. This sensory deficit often leads to unnoticed minor trauma; in the tropical climate of Vietnam, these neglected wounds are highly susceptible to infection, which likely explains the relatively high prevalence of infection observed in most limbs in this study. As sensory loss, infection, and tissue loss progress, the diabetic foot condition deteriorates, leading to an advancement in WIfI stage. However, since infection and tissue loss are direct components of the WIfI classification, the statistical association between these variables and the WIfI stage merely reflects the internal structure of the classification system, whereas LOPS is an issue that warrants more attention in the future.

TG, Hb and LDL-C levels were found to be statistically significantly associated with the WIfI stage (TG: p=0.01; Hb: p=0.016; LDL-C: p=0.008). These findings align with those reported by William P. Robinson et al., [12] who observed similar significant associations for Hb (p<0.001) and hyperlipidemia (p=0.002). This can be explained by the fact that more severe anemia reduces the oxygen-carrying capacity of the blood, leading to compromised tissue perfusion in the foot and thereby exacerbating ischemia. Furthermore, dyslipidemia is a well-established risk factor for atherosclerosis; over the long term, this impairs arterial perfusion and worsens ischemia, ultimately contributing to a more advanced WIfI stage.

4.4. Association between clinical outcomes and risk factors

Our analysis revealed significant associations between clinical outcomes and loss of protective sensation (LOPS) as assessed by the monofilament test (p = 0.018), the tuning fork test (p = 0.003), and the Ipswich Touch Test (p = 0.018). Although medical literature directly linking LOPS to clinical outcomes in diabetic foot disease remains limited, it is plausible that the presence of LOPS contributes to higher WIfI stages. Consequently, patients with more advanced WIfI staging are more susceptible to adverse clinical events, such as major amputation or mortality.

4.5. Correlation between limb perfusion indices and clinical outcomes

ROC analysis demonstrated that ABI had low predictive value and was not statistically significant at 1 year. Conversely, TBI reached statistical significance at 1 year (AUC = 74.4%; p = 0.021), with fair sensitivity and specificity. TP showed moderate predictive value at 1 year (AUC = 69.5%) but did not reach statistical significance (p > 0.05). Currently, there is a lack of literature addressing this discrepancy. However, we hypothesize that this may stem from the distal-to-proximal progression of peripheral arterial disease, where pathological changes typically manifest in the toes before subsequently affecting the foot and ankle. This suggests the potential superiority of TBI and TP over ABI, as toe pressures may decline before significant alterations are detected at the ankle level. Furthermore, TBI provides a more robust index than absolute TP by incorporating the brachial blood pressure ratio. For instance, in two patients with identical absolute TP values, the individual with a lower TBI would be clinically considered to have more severe ischemia. Therefore, from a pathophysiological standpoint, TBI provides a more comprehensive and accurate reflection of ischemia compared to absolute TP. However, the rate of loss to follow-up in our study was relatively high, which could introduce significant bias. Coupled with the small number of limbs followed, more data from future studies are needed to confirm these hypotheses.

4.6. Limitations

This study has several limitations. First, it was conducted at a single center, which limits the generalizability of our findings compared to multi-center studies, despite the geographical diversity of our patient population, who originated from various provinces across Vietnam. Second, our cohort consisted entirely of hospitalized inpatients; therefore, disease severity may be higher than that observed in outpatient settings, potentially introducing selection bias. Finally, despite efforts to conduct longitudinal follow-up, we encountered a significant rate of loss to follow-up, with only a small proportion of the original cross-sectional cohort successfully monitored. We aim to address these issues in future research.

5. CONCLUSION

In our study, diabetic foot disease, classified using the WIfI system, demonstrated a high prevalence of ischemia and infection, with a significant proportion of patients presenting with WIfI stage 4 (high). Clinical factors strongly associated with WIfI stages included LOPS, tissue loss, and infection. Notably, LOPS was significantly correlated with adverse clinical outcomes, specifically amputation and mortality. Our findings suggest that TBI plays a prognostic role in predicting these adverse events as an initial step. As a crucial clinical factor, TBI warrants further consideration for routine integration into clinical practice.

Conflict of interest statement

The authors declare that there is no conflict of interest regarding the research, authorship, and publication of this article.

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