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Type 2 Diabetes Mellitus Status with Ankle-Brachial Index among Patients with Diabetic Foot Ulcer at Universitas Airlangga Hospital, Surabaya

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ABSTRACT

Introduction: Diabetic foot ulcer (DFU) is one of the most significant complications of uncontrolled type 2 diabetes mellitus (T2DM) that may affect a patient's prognosis and quality of life. This study aimed to identify the association between diabetic status, DFU severity, and other clinical factors with ankle-brachial index (ABI) score and category.
Methods: This was a cross-sectional study under a consecutive sampling frame conducted from 1 November 2022 to 31 January 2023 at Universitas Airlangga Hospital, Surabaya. Primary data for ABI were measured from T2DM patients with DFU in the Thoracic and Cardiovascular Polyclinic. Meanwhile, secondary clinical data were collected from the Department of Internal Medicine based on the inclusion and exclusion criteria specified in the patient's medical records. The International Business Machines Corporation (IBM) Statistical Package for Social Sciences (SPSS) version 26 was utilized for the statistical analysis.
Results: Out of 30 included patients, 63.33% had uncontrolled diabetic status, and the average ABI score was 0.999 ± 0.19. DFU severity was significantly associated with the ABI score and ABI category. Patients indicated with angioplasty exhibited a markedly lower ABI score than those without (mean 0.32 vs 1.01; $p < 0.001$). Indication of angioplasty was the only clinical factor significantly associated with a lower ABI score ($p < 0.001$).
Conclusion: The status of T2DM was unrelated to ABI. Future research is recommended to advance the understanding of peripheral artery disease in diabetic foot ulcer patients.

Highlights:
1. ABI was not influenced by diabetic status due to potential confounders.
2. A more severe form of diabetic ulcer was associated with a lower ABI value.

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Introduction

Diabetes mellitus (DM) is a chronic metabolic disease affecting 10.3 million people in Indonesia every year, making it the sixth country with the highest incidence in the world.[1,2] Based on the Indonesian Basic Health Study (Riskesdas), there was a significant increase in DM prevalence from 6.9% in 2013 to 8.5% in 2018.[3] One of the most common complications caused by DM is diabetic foot ulcers (DFU). DFU are lesions that occur in patients with DM due to microvascular and macrovascular complications.[4,5]

The occurrence of DFU is often associated with other cardiovascular diseases, including peripheral artery disease (PAD). PAD is also linked to worse prognosis in patients with DFU. One commonly used evaluation test for individuals with DM and PAD is measuring the ankle-brachial index (ABI). ABI is the ankle systolic blood pressure (BP) ratio to brachial systolic BP. It is widely used to assess the severity of PAD and occlusions in the legs.[6] A lower ABI value indicates a more severe form of PAD, while a higher than normal ABI value indicates calcification/vessel hardening. Prior studies had emphasized the application of ABI in DFU patients. A study by Aulia, *et al.* (2019) demonstrated a significant positive correlation between ABI values and the Wagner classification of diabetic foot severity. This suggests that the ABI value tends to decrease as the duration of DM increases.[7] However, the association between glycemic control and ABI has not yet been established in prior studies.

Knowledge about the relationship between ABI values and diabetic status in DFU is crucial for healthcare professionals in maximizing the quality of healthcare services for patients. ABI values can provide a promising research avenue to explore vascular pathomechanism in DFU cases. Therefore, this study aimed to determine the association between type 2 DM (T2DM) status and ABI values in patients with DFU at Universitas Airlangga Hospital, Surabaya. By establishing such a link, this investigation could contribute significantly to refining the management and care protocols for individuals afflicted by DFU.[6]

Methods

Study Design and Setting

This cross-sectional study was conducted for a three-month period from 1 November 2022 to 31 January 2023 in the Thoracic and Cardiovascular Polyclinic of Universitas Airlangga Hospital, Surabaya. This study adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cross-sectional studies.[8]

Study Participants

Electronic medical records documenting the demographic information, diabetic status, and other related history were then retrieved from each eligible participant. The inclusion criteria for the study participants were T2DM patients who were clinically diagnosed with DFU in 2022. The evaluation of the patient's diabetic status was based on the standard procedures performed at Universitas Airlangga Hospital, Surabaya. The severity of DFU was defined by the Wagner classification. The exclusion criteria for the study participants were incomplete clinical data in the medical records and patient's medical records were not found.

Operational Definitions

T2DM status includes controlled and uncontrolled DM. T2DM is defined as uncontrolled if it meets any of the following criteria, (1) Fasting blood glucose >126 mg/dL or (2) 2-hour postprandial blood glucose >180 mg/dL or 3) HbA1C >7% (if HbA1C is not available, estimated average glucose [eAG] value may be considered).[9] The classification of DFU severity was conducted based on the Meggitt-Wagner system (Table 1).[10]

Table 1. Wagner classification of DFU grade

Wagner Grade	Description
Grade 0	No Ulcer in high-risk foot
Grade 1	Superficial ulcer, involving the entire thickness of the skin
Grade 2	Deep ulcer, involving muscles and ligaments, no bony involvement or abscess
Grade 3	Deep ulcer with cellulitis or abscess, often accompanied with osteomyelitis
Grade 4	Localized gangrene
Grade 5	Extensive gangrene, involving the entire foot surface

Source: Research data, processed

ABI is the ratio comparison of the highest systolic BP in the ankle and the systolic BP in the arm to identify arterial insufficiency. ABI scores categorized according to the European Society of Cardiology (ESC) 2017[11] and American Heart Association (AHA) 2016[12] consensus are as follows, low (≤0.9), borderline (0.9-1.0), normal (1.0-1.4), and non-compressible (>1.4).

ABI Measurement

Primary data, ABI, were measured from T2DM patients with DFU in the Thoracic and Cardiovascular Polyclinic of Universitas Airlangga Hospital, Surabaya, in 2022. Secondary clinical data of T2DM patients with DFU were collected from the Department of Internal Medicine, Universitas Airlangga Hospital, Surabaya, in 2022, based on the inclusion and exclusion criteria specified in the patient's medical records.

Statistical Analysis

The data analysis process in this study was conducted using the International Business Machines Corporation (IBM) Statistical Package for Social Sciences (SPSS) version 26.[13] Statistical analysis variables include independent t-test for normally distributed variables with two encompassed various tests, including Fisher's exact test for non-parametric, nominal categories, one-way analysis of variance (ANOVA) for normally distributed variables with more than two categories, Kruskal-Wallis test for non-parametric, ordinal variables with more than

two categories, and Spearman's rank test for assessing linear correlation between two continuous variables, especially when they are not normally distributed.

Results

Baseline Characteristics

Table 2 summarizes the clinical profile of DFU patients treated in the Thoracic and Cardiovascular Polyclinic of Universitas Airlangga Hospital, Surabaya, from November 2022 to January 2023. Out of 30 included patients, the majority of patients were male (60%), with an average age of 56.8 ± 11.22 years old. Based on the most recent diabetic status, 63.3% of the patients were categorized into the uncontrolled diabetes group. The patients were undergoing different types of DM pharmacological treatments, including oral antidiabetics (OAD) only (30.0%), insulin only (63.3%), or the combination of OAD and insulin (6.7%). The most common insulin drugs being actively consumed was ryzodeg (ultralong-acting insulin), followed by novorapid (rapid-acting insulin) and levemir (long-acting insulin), while the most common OAD was metformin and glimepiride, followed by thiazolidinedione and acarbose.

Table 2. Baseline characteristics of the included study participants (n = 30)

Clinical Profile	n (%)
Sex	
Male	18 (60.0%)
Female	12 (40.0%)
Age (years old)	
36-45	6 (20.0%)
46-55	10 (33.3%)
56-65	8 (26.7%)
66-75	4 (13.3%)
>75	2 (6.7%)
Diabetic Status	
Controlled	11 (36.7%)
Uncontrolled	19 (63.3%)
Pharmacological Treatment	
OAD	9 (30.0%)
Insulin	19 (63.3%)
OAD + insulin	2 (6.7%)
DFU Severity	
Wagner I	1 (3.3%)
Wagner II	14 (46.7%)
Wagner III	12 (40.0%)
Wagner IV	3 (10.0%)
History of Secondary Infection	19 (63.3%)
History of Digit Amputation	16 (53.3%)
Indication of Angioplasty	1 (3.3%)
ABI Score Category	
≤0.90 (low)	5 (16.7%)
0.91 - 0.99 (borderline)	9 (30.0%)
1.0 - 1.40 (normal)	16 (53.3%)

N: total; n: frequency; OAD: oral antidiabetics; DFU: diabetic foot ulcer; ABI: ankle-brachial index
Source: Research data, processed

Based on the Wagner classification of DFU severity, the patients were mostly categorized into Wagner II (46.7%), Wagner III (40%), Wagner IV (10%), and Wagner I, respectively (3.3%). This study also identified 19 patients (63.3%) with history of previous secondary infection, 16 patients (53.3%) with history of digit amputation, and one patient (3.3%) with indication of angioplasty. The ABI score from 30 patients had an average of 0.99 ± 0.19 and was normally distributed on Kolmogorov-Smirnov's test (p = 0.121). Following the ESC and AHA consensus classification, this study found 16 patients (53.3%) with normal ABI category, 9 patients (30%) with borderline ABI category, and 5 patients (16.7%) with low ABI category.

Association between DFU severity and ABI

Based on Table 3, the average ABI score based on each DFU severity degree was 1.19, 1.04 ± 0.16, 0.98 ± 0.12, and 0.71 ± 0.34 for Wagner I to Wagner IV, respectively. DFU severity was found to be inversely related to the ABI score (r -0.478; p = 0.008).

Association between diabetic status and ABI

Patients with controlled T2DM had an average ABI score of 1.02 ± 0.16, while those with uncontrolled status had an average ABI score of 0.97 ± 0.21. No significant association was identified between diabetic status with ABI score (p = 0.511) (Table 4).

Table 3. Association between DFU severity and ABI

DFU Severity	ABI Score (Mean ± SD)	Spearman's Correlation	
		r	p
Wagner I	1.19	-0.478	0.008
Wagner II	1.04 ± 0.16		
Wagner III	0.98 ± 0.12		
Wagner IV	0.71 ± 0.34		

DFU: Diabetic foot ulcer; ABI: Ankle-brachial index; SD: standard deviation; r: Spearman's rho correlation coefficient
Source: Research data, processed

Association between other clinical factors and ABI

To mitigate confounding effects on ABI values, this study assessed the association of various clinical factors. Patients with indication of angioplasty had a significantly lower ABI values compared to those without (p < 0.001). However, there was no significant association between sex, age group, pharmacological treatment, history of secondary infection, and history of amputation with ABI (Table 5).

Table 4. Causes of mortality

Diabetic Status	ABI Score (Mean ± SD)	Independent t-test p-value[a]
Controlled	1.02 ± 0.16	0.511
Uncontrolled	0.97 ± 0.21	

ABI: Ankle-brachial index; SD: standard deviation
Source: Research data, processed

Discussion

This study found no significant association between T2DM and ABI. In line with these findings, a previous study also reported no relationship between ABI and fasting blood glucose (p = 0.128) or HbA1C levels (p = 0.232) in T2DM patients.[14] Random blood glucose was not associated with ABI score (p = 0.0533) among T2DM patients originating from Kenali Besar Health Center, Jambi.[15] It is important to highlight that while some evidence supports the use of random blood glucose of >200 mg/dL to define uncontrolled diabetes, the parameter

can vary significantly based on activity level, dietary patterns, and actively consumed drugs.[16,17] The severity of DFU was found to have a significant association with both the ABI score and category. This finding is consistent with a previous study conducted at Wahidin Sudirohusodo Hospital, Makassar, which demonstrated a correlation between DFU severity and ABI.[7]

Table 5. Association between clinical profile and ABI

Clinical Profile	ABI Score (Mean ± SD)	p-value[a]
Sex		
Male	1.01 ± 0.22	0.381
Female	0.95 ± 0.14	
Age (years old)		
36-45	1.05 ± 0.11	0.939
46-55	0.99 ± 0.17	
56-65	0.95 ± 0.29	
66-75	0.99 ± 0.08	
>75	0.96 ± 0.19	
T2DM Treatment		
OAD	0.99 ± 0.19	0.900
Insulin	0.98 ± 0.20	
OAD + insulin	1.05 ± 0.02	
History of Secondary Infection		
Yes	0.96 ± 0.22	0.341
No	1.03 ± 0.12	
History of Digit Amputation		
Yes	0.96 ± 0.23	0.360
No	1.02 ± 0.14	
Indication of Angioplasty		
Yes	0.32	<0.001
No	1.01 ± 0.15	

[a]Independent T-test if group = 2 or one-way ANOVA if group >2
DFU: Diabetic foot ulcer; ABI: Ankle-brachial index; SD: standard deviation; n: amount
Source: Research data, processed

Angiopathy and neuropathy are the underlying mechanism that occurred during the manifestation of DFU. Neuropathic-type DFU typically exhibit a normal ABI score, while cases with angiopathic involvement experience a decrease in ABI, which leads to tissue ischemia. Consequently, an increase in DFU severity corresponds to a higher degree of tissue ischemia.[18]

In this study, no significant association was found between the sex of DFU patients and both the value and category of ABI. These findings are consistent with previous studies conducted in South Jakarta and Boyolali, which stated that sex had no significant relationship with ABI values in the elderly age group (p = 1.000) and adults (p = 1.000), respectively.[19,20] In contrast, a study in the general population in the United States (US) showed that ABI values were 0.03 lower in females compared to males (OR 1.34; 95% CI [1.04–1.72]; p = 0.025).[21] Previous studies also demonstrated that although not explicitly explaining these differences, the influence of sex on ABI values is suspected to be due to the higher height of males, which tends to exceed that of females, leading to a greater ankle pressure gradient.[21] Additionally, females tend to have lower degrees of arterial calcification compared to males in the same age group, resulting in an increased ABI value.[22]

In this study, no significant association was found between age and ABI value categories. These findings are consistent with previous studies reporting no significant association between age and ABI value categories.[23] Kapoor, *et al.* (2018) found that with an increase in age by 10 years, there was a decrease in ABI value by 0.024 in the general population.[21] In this study, no association was found between a history of secondary infections and the values and categories of ABI. The atherosclerosis risk in communities (ARIC) study showed that peripheral artery disease (based on clinical history or ABI ≤0.90) and borderline ABI values (0.91-1.00) are independent risk factors (adjusted HR 1.66; 95% CI [1.42-1.94] and adjusted HR 1.75; 95% CI [1.47-2.07], respectively) for the occurrence of infections, including cellulitis, bloodstream infections, pneumonia, and urinary tract infections.[24] Additionally, surgical procedures often associated with this patient group increase the risk of surgical site infections (SSI).[25] Current evidence suggests that infections from bacteria, fungi, and viruses can lead to vascular wall inflammation and progression towards peripheral arterial disease by direct contamination, increased systemic immune reactions, or a combination of both mechanisms.[26] One of the most severe clinical manifestations caused by secondary infections in DFU is sepsis and its progression to organ failure.

In this study, no association was found between a history of amputation and the values and categories of ABI. This lack of association may be attributed to the low prevalence of amputation history among the participants admitted to the ward, potentially limiting its representation of the true impact of these variables on ABI. However, evidence reported that T2DM patients with abnormal ABI values (<0.9) had a tendency to undergo major lower extremity amputations compared to minor amputations (80% vs 47.8%; p < 0.01).[27,28] Another multivariate regression analysis in the ARIC study showed that the risk of ischemic foot amputation significantly increased in individuals with ABI values ≤0.9 (HR 2.72; 95% CI [1.25-5.91]), 0.91-1.00 (HR 2.02; 95% CI [1.13-3.63]), and 1.01-1.10 (HR 1.73; 95% CI [1.07-2.79]) compared to individuals with normal ABI values.[29] A study found that individuals with normal ABI values (0.91-1.30) tended to have healing (p < 0.05), while those with severe ABI values (≤0.40) tended to experience failure in trans metatarsal amputation procedures (p < 0.01).[30]

This study demonstrated significant association between indication of angioplasty with ABI. This observation can be attributed to the fact that angioplasty procedures are typically reserved for individuals with substantial vascular blockages or stenosis who exhibit inadequate treatment response or experience a considerable impact on their daily activities.[31] However, a study actually showed that individuals with abnormal ABI values (<0.9 or ≥1.4) and/or TcPO2 <30 mmHg were more likely to undergo vascular interventions compared to those

with ABI values in the normal range (p = 0.000).[32] A study conducted in the Japanese population showed that individuals with low ABI values (<0.9) were more likely to undergo revascularization due to PAD compared to individuals with ABI values in the normal range (0.9≤ABI<1.4; 51.7% vs 0%; p < 0.001).[33]

Strength and Limitations

One notable strength of this study lies in its comprehensive and systematic approach to evaluate the association between ABI and diabetic status, in which it became one of the first piece of evidence evaluating the association between T2DM status with ABI among DFU subjects in the Indonesian population. While this study provides valuable insights into the topic at hand, it is important to acknowledge its inherent limitations. The small sample size may be one of the major contributors to the non-significance identified across several results. The authors were unable to include several confounding factors into the analysis due to the incomplete data available on the electronic medical health records.

Conclusion

ABI was not associated with T2DM status among DFU patients. However, DFU severity was found to be inversely related to ABI score and category. Patients presenting with the indication of angioplasty had a lower ABI score compared to those without.

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Conflict of Interest
The authors declared there is no conflict of interest.

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Ethical Clearance
This study was ethically approved by the Health Research Ethics Committee of Universitas Airlangga Hospital, Surabaya (No. 103/KEP/2022) on 14-10-2022.

Authors' Contributions
Conceptualization: HAA, DHL, SDS. Methodology: HAA, DHL, SDS. Formal analysis and investigation: HAA. Original draft preparation: HAA, DHL, SDS, BUU, PBD. Review and editing: HAA, DHL, SDS, BUU, PBD. Funding acquisition: HAA, DHL. Resources: DHL, SDS, BUU. Supervision: DHL, SDS, BUU. Discussion: FY, MFA, AW. All authors reviewed and approved the final version of the manuscript.

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