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Glycated Hemoglobin Level and Body Mass Index Correlation with Peripheral Artery Disease in Patients with Type 2 Diabetes Mellitus at Waled Hospital, Cirebon, Indonesia

Tania Auliya[1]*, Nihayatul Amaliyah[2], Menik Herdwiyanti[2]

[1] Faculty of Medicine, Universitas Swadaya Gunung Jati, Indonesia,
[2,]Department of Internal Medicine, Faculty of Medicine, Universitas Swadaya Gunung Jati, Indonesia.

***Corresponding author's e-mail: taniaauliya41@gmail.com**
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ABSTRACT

Background: Peripheral Artery Disease (PAD) is a condition that reduces blood flow to the lower extremities and is primarily caused by atherosclerosis. PAD is one of the complications of Diabetes Mellitus (DM). Diabetics have an 11.6 times more likely to develop PAD than those without diabetes. Glycated haemoglobin (HbA1c) levels >7% are at a higher risk of chronic complications. Obesity and overweight also raise the risk of developing PAD disease. However, research on the correlation between Body Mass Index (BMI) and PAD remains unclear and controversial**.**

Aims: To analyze the correlation between HbA1c levels and BMI with the incidence of Peripheral Artery Disease in patients with type 2 Diabetes Mellitus at Waled Hospital.

Methods: This is an analytical observational study with a cross-sectional design. Data was collected on patients diagnosed with type 2 Diabetes Mellitus at the Internal Medicine Clinic at Waled Hospital in June - July 2024. A total sample of 77 was obtained using consecutive sampling. The inclusion criteria were type 2 DM, aged 19-60 years, and medical record data equipped with the HbA1c levels for at least the last 3 months prior to data collection. The exclusion criteria were patients with a history of diabetic ulcers, amputation and limb disability, Acute Coronary Syndrome, stroke, kidney failure, recurrent anaemia, and blood transfusions in the last 3 months. Primary data was gathered through an ABI examination, while secondary data was obtained from medical records. The data was analysed using the Spearman correlation test.

Results: Patients had poor HbA1c control (51.9%), moderate HbA1c control (29.9%) and good HbA1c control (18.2%), with the majority of patients had normal BMI (39%) followed by obese I (22.1%), overweight and obese II (16.9%). Our study showed that the distribution of PAD levels was severe (0%), moderate (3.9%), mild (44.2%), normal (46.8%), and arteriosclerotic (5.2%). The correlation test showed p-0.789 (p> 0.05) for HbA1c levels with PAD and p- 0.653 (p>0.05) for BMI with PAD.

Conclusion: There was no association between glycated hemoglobin or Body Mass Index values and the incidence of PAD in patients with type 2 Diabetes Mellitus at Waled Hospital, Cirebon, Indonesia.

Keywords: *Glycated Hemoglobin, HbA1c, Body Mass Index, Peripheral Artery Disease, Diabetes Mellitus.*
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1. Introduction

Peripheral Artery Disease (PAD) is a condition that reduces blood flow to the lower extremities and is mostly caused by atherosclerosis (Widiastuti et al., 2022). According to the Global Burden Disease, the global prevalence of PAD has increased from 65.8 million in 1990 to 113 million in 2019 (The Lancet Global Health, 2023). Based on a systematic review, the number of patients with PAD in 2015 was approximately 236 million. The increase in prevalence reached more than 17% (30 million people) over 5 years (Horvath et al., 2022). PAD affects up to 172 million people with PAD in countries with middle to lower socio-demographics, making it a global problems (Criqui et al., 2021). The prevalence of PAD in Indonesia is one million Indonesians; around 13,807 people suffer from PAD (Said et al., 2021).

PAD is one of the macrovascular complications of Diabetes Mellitus (Perkeni, 2021). Diabetes Mellitus (DM) is a group of metabolic diseases distinguished by hyperglycemia. According to the International Diabetes Federation (IDF), around 537 million people might have diabetes in 2021, with a projected total of 643 million people by 2030. The prevalence of diabetes in Indonesia in 2021, according to the IDF, shows as many as 179 million people with a range between 20 and 79 years old (IDF 2021). WHO estimates the number of people with DM type 2 in Indonesia would rise from 8.4 million in 2000 to about 21.3 million by 2030 (Perkeni, 2021). The prevalence of DM patients in Indonesia diagnosed as >15 years old was 6.9% in 2013 and increased to 8.5% in 2018. West Java Province has around 186,809 people diagnosed with DMT2 in 2018. The number of people diagnosed with diabetes in Cirebon Regency in 2018 was 0.87% of the total in West Java (Kemenkes RI, 2018). The results of a preliminary study conducted at Waled Hospital, Cirebon Regency, in February 2020 found that the number of type 2 diabetes mellitus patients in 2018 was 1,807 (Anisa et al., 2021).

Chronic hyperglycemia impairs vascular endothelial function. Diabetics have an 11.6 times greater risk of developing PAD compared to non-diabetics (Said et al., 2021). About 25-30% of DM patients will develop PAD, compared to 15% of non-DM patients (Ismail et al., 2021). Patients with DM with PAD have a 5 times higher risk of ischemia, tissue necrosis, and amputation, resulting in decreased activity and decreased quality of life (Criqui et al., 2021; Puspitasari et al., 2023). Therefore, PAD screening is needed to prevent amputation. PAD can be detected using the Ankle Brachial Index (ABI) results. The ABI examination is a non-invasive examination and has a sensitivity of 63.5% and a specificity of 89.3% in diagnosing PAD (Normahani et al., 2021).

Risk factors for PAD in type 2 DM patients increase with age, gender, length of DM, poor glycemic control, hypertension, lack of physical activity, high Body Mass Index (BMI), and hypercholesterolemia (Widiastuti et al., 2022). The American Diabetes Association (ADA) recommends using the glycated haemoglobin (HbA1c) test to assess if a person's blood sugar control is good or bad. Patients with HbA1c levels >7% have an increased chance of having chronic complications (Oktalia et al., 2021). One of the factors that cause macrovascular disorders is obesity. Obesity and overweight can raise the chance of developing PAD, which refers to atherosclerosis of the lower extremity blood vessels (Hefron et al., 2020). Body Mass Index (BMI) measurement is a simple and widely used method for determining obesity (Tursinawati et al., 2020). According to the Framingham study, BMI has a greater correlation with intermittent claudications in men. Those with a low BMI in this study are believed to be at a higher risk, even though women with extreme BMIs (whether low or high weight) are more likely to experience this condition. ABI and BMI are found to be significantly correlated in the Arterial Edinburgh analysis. According to research on people with diabetes mellitus, Taiwanese subjects with a higher BMI also have a higher risk of PAD (Lempesis et al., 2023). However, in other studies conducted by Savitri et al. (2020), waist circumference is used to determine obesity in addition to BMI.

2. Methods

This study used observational analysis using a cross-sectional design. Data collection was carried out at the Internal Medicine Clinic of Waled Hospital from June to July 2024. Sampling was selected using a consecutive sampling technique. Patients having a diagnosis of type 2 diabetes mellitus aged 19-60 years, willing to participate in the trial, and medical record data including HbA1c readings for at least the past three months prior to data collection were all acceptable and included in the inclusion criteria. The exclusion criteria in this study

were patients with a history of diabetic ulcers, amputation and limb disability, Acute Coronary Syndrome, stroke, kidney failure, recurrent anaemia, and blood transfusions in the last 3 months. Patients with exclusion criteria are excluded because they can alter the results of the ABI examination, making them inaccurate. This can be caused by circulatory disorders that occur due to other vascular problems in the brain or heart, a history of amputation, or diabetic ulcers resulting in one or both legs not having arteries or body parts that can be used to measure the legs. Furthermore, kidney failure and recurrent anaemia can affect HbA1c results. The samples in this study were calculated using cross-sectional calculations, with a prevalence of type 2 Diabetes Mellitus of 28% and a 10% acceptable error with a 95% confidence interval. As a result, the minimum sample size was calculated as n = 77.

The data of patient demographics, such as age, gender, and medical history (smoking and duration of diabetes) were asked directly to them. Secondary data from medical records were used to acquire information about HbA1c levels and type 2 DM. HbA1c levels are classified as good (<6.5), moderate (6.5-8), and poor (>8) (Setiati et al., 2014). Data Body Mass Index (BMI) was obtained by calculating the body weight divided by height squared. The BMI is categorized according to the WHO Asia-Pacific classification: underweight < 18.5 kg/m2, normal 18.5 – 22.9 kg/m2, Overweight 23,0-24,9 kg/m2, Obese I 25,0 - 29,9 kg/m2, and Obese II ≥30 kg/m2. The limitation of using BMI is that the data obtained does not differentiate between fat and muscle mass, nor does not it identify the distribution of body fat. Data on Peripheral Artery Disease (PAD) were obtained through the Ankle Brachial Index (ABI) examination. The ABI examination assesses the systolic blood pressure ratio between the ankle and upper arm using a sphygmomanometer and vascular Doppler. The researcher performed an ABI examination and calculated the outcome using the formula of the highest leg systolic blood pressure divided by the highest upper arm blood pressure. The results of the ABI assessment were Severe PAD <0.4, Moderate PAD 0.40-0.69, Mild PAD 0.70-0.90, Normal 0.9-1.30, and Arteriosclerotic >1.30 (Perkeni, 2021).

The independent variables in this study were glycated haemoglobin levels and Body Mass Index. The dependent variable in this study was Peripheral Artery Disease. Following data collection, a univariate analysis was performed to explain the frequency distribution of each variable. The bivariate analysis examines the correlation between glycated haemoglobin levels, Body Mass Index, and Peripheral Arterial Disease. The data was then processed using Spearman's correlation test because, in this research, the data obtained was categorical data with an ordinal scale. In hypothesis testing, p-value <0.05 indicates a relationship between the independent and dependent variables. Meanwhile, if the p-value >0.05, it indicates no relationship between the independent and dependent variables. This study has met the ethical requirements of the Ethics Commission of Waled Hospital with research number 000.9.2/036/KEPK/V/2024.

3. Results

Respondent characteristics

Table 1 shows that of the 77 respondents, 57 people (74%) are female and 27 people (26%) are male. The majority of people are between the ages of 46 and 55, accounting for 40 (51.9%). Patients suffering from type 2 DM obtained an average duration of 5.1 years, and duration <5 years was more dominant, namely 40 people (51.9%). The majority of patients do not smoke as many as 69 people (89.6%). The most blood pressure in the hypertension category is 45 people (58.4%). The patient's blood glucose obtained an average result of 209.6 mg/dl.

Univariate analysis

According to Table 2, the majority of HbA1c levels are poor in up to 40 people (51.9%). This is consistent with the previous study, a study conducted by Puspitasari et al. (2023), in which the findings of the distribution of HbA1c values were achieved by patients with poor HbA1c control as much as (77%), compared to controlled HbA1c as much as (23%).

Table 1. Characteristic of the respondents

Characteristics	Frequency(n)	Percentage (%)	Average
Gender			
Male	20	26	
Female	57	74	
Age			
19 – 25 years old	0	0.0	
26 – 35 years old	2	2.6	
36 – 45 years old	12	15.6	
46 – 55 years old	40	51.9	
56 – 60 years old	23	29.9	
Duration of Diabetes Mellitus			5.1
< 5 years	40	51.9	
≥ 5 years	37	48.1	
Smoking			
Yes	8	10.4	
No	69	89.6	
Blood Pressure			
Normal (<130 mmHg and/or <85 mmHg)	18	23.4	
Pre-hypertension (130-139 mmHg and/or 85-89 mmHg)	14	18.2	
Hypertension (≥140 mmHg and/or ≥ 90 mmHg)	45	58.4	
Blood Glucose level			209.6 (73-444)

Table 2. HbA1c Frequency distribution

HbA1c	Frequency (n)	Percentage (%)
Good	14	18.2
Moderate	23	29.9
Poor	40	51.9
Total	77	100.0

Table 3 shows that the majority of patients in the normal Body Mass Index category are 30 people (39%). According to research conducted by Tursinawati et al. (2020), BMI data were obtained with the following categories: Underweight 0%, Normal BMI 40%, Overweight 20%, and Obese 40%.

Table 3. Body Mass Index (BMI) frequency distribution

Body Mass Index	Frequency (n)	Percentage (%)
Underweight	4	5.2
Normal	30	39
Overweight	13	16.9
Obese I	17	22.1
Obese II	13	16.9
Total	77	100.0

As indicated in Table 4, the majority of type 2 diabetes patients have Peripheral Artery Disease (PAD), with 36 people having no PAD (46.8%), followed by 34 people having mild PAD (44.2%). This is consistent with the research conducted by Aminudin's (2021) findings on the distribution of the most PAD values in patients with the normal category, which included 74 people (52.5%), followed by 49 people (34.8%) with mild PAD, 14 people (9.9%) with moderate PAD, and 4 people (2.8%) with vascular PAD.

Table 4. Peripheral Artery disease (PAD)Frequency distribution

Peripheral Artery Disease	Frequency (n)	Percentage (%)
Arterisclerotic	4	5.2
Normal	36	46.8
Mild PAD	34	44.2
Moderate PAD	3	3.9
Severe PAD	0	0
Total	77	100.0

Bivariate analysis

According to the results presented in Table 5, 40 out of 77 respondents have poor HbA1c control levels, with 17 individuals (22.1%) not experiencing PAD, 18 individuals (23.4%) experiencing mild PAD, and 2 individuals (2.6%) experiencing moderate PAD. The results show no significant difference. The results are similar in patients with both moderate and good HbA1c levels. The average difference in results between normal patients and those with mild PAD in each HbA1c category was 1-2 people. The research, using Spearman's correlation test, yielded a p-value of 0.798 (p>0.05), indicating that there is no significant correlation between glycated haemoglobin and the incidence of peripheral arterial disease. Figure 1 shows a graph of the increase in mild PAD results and no PAD with HbA1c control levels. Patients with moderate PAD begin to exhibit moderate and poor HbA1c levels.

Table 5. The Results Analysis of the Correlation between HbA1c and Peripheral Artery Disease (PAD)

HbA1c Levels		*Peripheral Artery Disease*					Total	*P value*	*r*
		Artery sclerotic	Normal	Mild	Moderate	Severe			
Good	**n**	0	8	6	0	0	14	0. 798	0.030
	%	0.0	10.4	7.8	0.0	0.0			
Moderate	**n**	1	11	10	1	0	23		
	%	1.3	14.3	13	1.3	0.0			
Poor	**n**	3	17	18	2	0	40		
	%	3.9	22.1	23.4	2.6	0.0			
Total	**n**	4	36	34	3	0	77		
	%	5.2	46.8	44.2	3.9	0.0			

According to Table 6, patients with a normal BMI category who did not have PAD accounted for 15 people (19.5%) of the 77 respondents. Therefore, the results obtained are still scattered. The difference in the number of normal patients compared to those experiencing mild PAD in each BMI category is 1-3 people. Patients experiencing moderate PAD were found among those with underweight, obese I, and obese II. There was one underweight patient (1.3%) in each PAD category. The results of the analysis Spearman's correlation test obtained a p-value of 0.653 (p>0.05), which indicates that there is no significant correlation between Body Mass Index and the incidence of Peripheral Artery Disease.

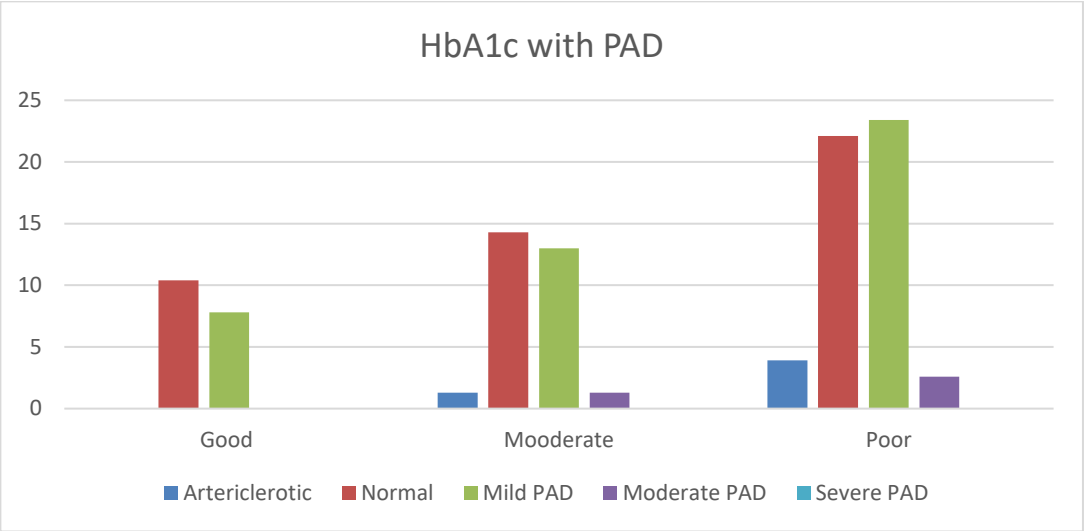

Figure 1. Bar Chart of the Correlation between HbA1c and Peripheral Artery Disease (PAD)

Table 6. The Analysis Results of the Correlation between HbA1c and Peripheral Artery Disease (PAD)

Body Mass Index		***Peripheral Artery Disease***					**Total**	***p value***	***r***
		Artery sclerotic	**Normal**	**Mild**	**Moderate**	**Severe**			
Underweight	**n**	1	1	1	1	0	4		
	%	1.3	1.3	1.3	1.3	0.0			
Normal	**n**	2	15	13	0	0	30		
	%	2.6	19.5	16.9	0.0	0.0			
Overweight	**n**	0	5	8	0	0	13	0.653	0.052
	%	0.0	6.5	10.4	0.0	0.0			
Obese I	**n**	0	9	7	1	0	17		
	%	0.0	11.7	9.1	1.3	0.0			
Obese II	**n**	1	6	5	1	0	13		
	%	1.3	7.8	6.5	1.3	0.0			
Total	**n**	4	36	34	3	0	77		
	%	5.2	46.8	44.2	3.9	0.0			

Figure 2 depicts a fluctuating graph for patients without PAD or normal, but those with mild PAD have a decreasing graph as their BMI category increases.

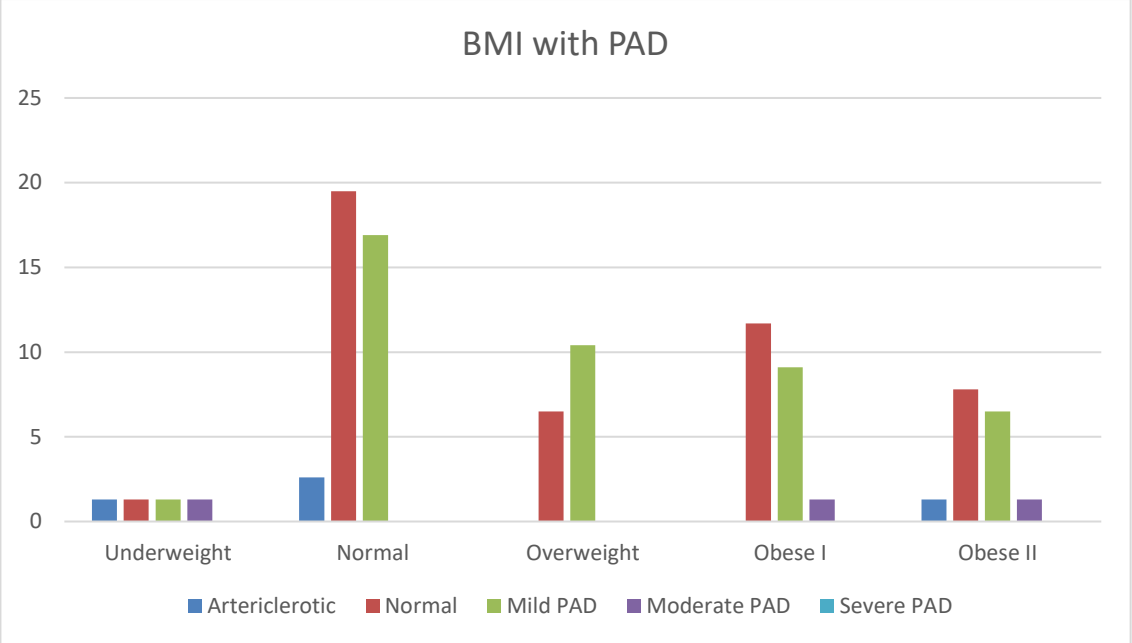

Figure 2. Bar Chart of the Correlation between BMI and Peripheral Artery Disease (PAD)

4. Discussion

In this study, it was revealed that most of respondents of type 2 DM patients who came to RSUD Waled were female, precisely 74%. These results are consistent with research conducted by Indrayana et al (2020), which found that up to 67.8% of patients were female. This is in accordance with the pathogenesis that women experience an imbalance in hormone levels when they enter menopause, leading to uncontrolled blood glucose levels (Widiastuti et al., 2022).

The age range of patients with type 2 DM in this study was mostly 46 - 55, specifically 40 people (51.9%), which is comparable to research by Oktalia et al. (2021). At the age of ≥45, intolerance to glucose may occur due to the reduced ability of pancreatic β cells to produce insulin (Widiastuti et al., 2022).

The results of this study are in line with a study conducted by Puspitasari et al. (2023) on type 2 DM patients at the Gatak Sukoharjo Health Center, Central Java, which found no significant relationship between HbA1c levels and the incidence of Peripheral Artery Disease. The analysis's findings could not give a comprehensive description of the population since, despite the use of variable categorisation and other analytical tests, the features of the respondents were comparable and there were only a few samples collected. In addition, a study conducted by Safitri et al. (2019) at Antonius Hospital Pontianak also found no significant relationship between HbA1c levels and the incidence of peripheral arterial disease with a p-value of 0.487.

Some factors can affect the results between HbA1c and the incidence of PAD. This could be due to the HbA1c value obtained when the patient was first diagnosed or the duration of the patient suffering from diabetes mellitus has not been long enough (Safitri et al., 2019, Cahyono et al., 2019). The majority of DM patients will develop ABI abnormalities when the disease has progressed for more than 5 years. This pathomechanism occurs due to glucotoxicosis over time, resulting in endothelial dysfunction and the formation of atherosclerosis (Kartikadewi et al., 2022). Research conducted by Lintang et al. (2020) found significant results between the length of time suffering from DM and the incidence of PAD with the average length of time respondents suffered from DM, which was 9.8 years, whereas research by Bharata et al. (2021) found no relationship between the length of DM and the incidence of PAD with the average length of time the respondents suffered from DM, which was 5.7 years. Thus, the insignificant results in this study can be attributed to the characteristics of the duration of suffering from DM of respondents, which is 5.1 years on average. Therefore, this duration is not long enough to cause PAD (Brahata et al., 2021).

In this study, the researcher did not evaluate the type of treatment and long of treatment the patient received. The routine use of Oral Hypoglycemic Drugs by DM patients can affect the correlation between HbA1c

and the incidence of PAD. One of these is the drug metformin, which, in addition to lowering glucose, metformin has non-glycemic effects such as endothelial function and cell proliferation. In individuals with type 2 diabetes mellitus, AMPK activation by metformin increases endothelial nitric oxide synthase (eNOS) activity, which directly impacts vascular endothelial protection (Poznyank et al., 2022)

Furthermore, because of the researcher's challenges in obtaining research samples, no control was provided for confounding factors such as cholesterol in this study. Increased total cholesterol, LDL cholesterol, and triglycerides are all independent risk factors for the PAD incident. Research conducted by Sabila et al. (2024) stated that DM patients with high total cholesterol levels tend to experience PAD. The presence of excess cholesterol components in nature triggers atherosclerosis activity, inhibiting the blood supply to the leg muscles. LDL cholesterol is the main atherogenic lipoprotein that contributes about 60-70% of the total cholesterol that causes atherosclerosis (Perkeni, 2019). According to the study, every 1 mg of LDL raised the incidence of PAD by 1.9% (Day et al., 2019). HDL, in particular, can activate endothelial nitric oxide synthase by stimulating specific signalling pathways, such as Akt and MAP kinase. This activation increases nitric oxide production, an important mediator in vascular homeostasis. Furthermore, HDL has a protective effect on endothelial cells by suppressing apoptosis through activation of the Akt pathway and inhibition of the enzyme caspase. HDL also inhibits the oxidation of low-density lipoprotein (LDL), thereby reducing its pro-atherogenic effects (Ruslim et al., 2023)

Another risk factor that affects the incidence of PAD is smoking. The study revealed that there was a 2.44 times increased risk in former smokers compared to non-smokers (Xu et al., 2024). This is because smoking causes endothelial cell dysfunction through decreased NO synthesis (Wang et al., 2021). In this study, it was found that almost all respondents did not smoke, namely 89.6%, so this risk factor could not describe the incidence of PAD.

In this study, only the ABI (Ankle Brachial Index) examination was performed to diagnose PAD. ABI examination has a sensitivity of 63.5% and a specificity of 89.3% (Normaharani et al., 2020). ABI examination is limited to mediocalcinosis, which is common in DM patients. Therefore, more diagnostic tests are needed. Other non-invasive tests include measuring the toe-brachial index (TBI) and visualising the tibial artery using duplex ultrasonography (Achim et al., 2022). This visual wave of the tibial artery has a sensitivity of 82.8% and specificity of 86.8%, allowing it to better describe vascular occlusive disease in more detail (Susilo et al., 2021).

In this study, the results of the correlation test showed that there was no significant correlation between Body Mass Index and incidence of Peripheral Artery Disease in type 2 DM patients at Waled Hospital with a p-value of 0.653. The results of this study are in line with research conducted by Tursinawati et al. (2020) with a case-control design and a p-value of 0.255. Researchers did not evaluate the physical activity of patients. Regular and measured physical activity has been shown to promote health (Aminudin et al., 2021). Physical activity has been shown to prevent vascular damage such as atherosclerosis due to changes in lipid and lipoprotein metabolism (Meyer et al., 2023). In addition, regular physical activity can improve insulin response, glucose tolerance, and blood pressure homeostasis (Kartikadewi et al., 2022). Low levels of physical activity are associated with several risk factors, including high blood pressure, increased arterial stiffness, increased waist circumference, and decreased HDL cholesterol (Gerage et al., 2019).

Research conducted by Junpei et al. (2021) found a correlation between BMI and PAD. There are differences in the characteristics of respondents in this study, namely the average age of respondents of elderly patients with hypertension. The lowest BMI value with PAD risk was estimated in those with BMI ≥ 25.7 kg/m2. Research conducted by Ileana et al. (2020) discovered a significant relationship between BMI and PAD with a large sample size of 1815 people and age criteria of ≥ 65 years. Obesity is thought to be one of the causes of insulin resistance. Obesity also promotes hyperplasia of perivascular adipose tissue, which leads to low NO levels and reduced endothelial function (Savitri et al., 2020).

Other studies, in addition to utilising BMI measurements, determine a person's obesity by measuring their waist circumference. Research conducted by Savitri et al. (2020) showed significant results of the correlation between central obesity and PAD. Visceral fat is more closely associated to the risk of PAD than BMI because it increases arterial stiffness, which leads to atherosclerosis (Taylor, 2021).

5. Conclusion

The study revealed that there was no significant correlation between glycated haemoglobin levels or Body Mass Index and the incidence of Peripheral Artery Disease in type 2 Diabetes Mellitus patients at Waled Hospital (p=0,798 and p=0,653). The small sample size and uneven distribution resulting from the short research period, uncontrolled confounding factors like the type and duration of DM treatment that impact the relationship between HbA1c levels and PAD events, lipid profiles from examination results that are not routinely performed, the inability to eliminate bias related to the use of DM drugs by patients, and the fact that PAD is only determined from ABI examinations and not followed by other PAD examinations are some of the limitations of this study. In addition, researchers did not evaluate the physical activity of patients.

Further research on confounding factors is required; the findings of this study can be expanded by include additional variables that influence the prevalence of PAD, such as profile lipid (total cholesterol and LDL), and the incidence of obesity can be assessed using central obesity measurements. Furthermore, an examination can be carried out using other standard diagnostic tools to determine PAD, such as a USG duplex or an ABI examination followed by other examinations. Based on the results of this study, healthcare practitioners are expected to educate patients on the importance of blood glucose control, particularly through HbA1c examinations to reduce the risk of DM complications, as well as perform ABI examinations as an initial screening for PAD diagnosis in health facilities.

Conflict of Interest

The authors declare no conflicts of interest.

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