ORIGINAL ARTICLE

Elevated HbA_{1c} level associated with disease severity and surgical extension in diabetic foot patients

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ABSTRACT

BACKGROUND: Diabetic foot is a complex syndrome that is associated with other diabetic complications, such as peripheral arterial disease and peripheral neuropathy. Optimization of plasma glucose and glycated hemoglobin (HbA_{1c}) is one of the main principles of standard care and treatment approaches in individuals with diabetes mellitus (DM). In this study, the relationship of HbA_{1c} level at the time of diagnosis was evaluated with diabetic foot disease severity score and surgical extension in patients with Type 2 DM.

METHODS: This study included 301 consecutive patients who were diagnosed with diabetic foot in the general surgery diabetic foot clinic and were hospitalized for surgery. The relationships between the HbA1c levels of the patients with the Wagner and PEDIS (Perfusion, Extent, Dept, Infection, Sensation) classification system grades, and the surgical procedures performed were analyzed and the treatment outcomes were evaluated.

RESULTS: It was determined that there was a 90% statistically significant relationship between HbA_{1c} values of ≥10.1% and the development of Wagner Grade 4 diabetic foot ulcer (DFU) (P=0.037). A strong statistically significant relationship at the rate of 85% was determined between HbA_{1c} values of ≥10.1% and the development of PEDIS Grade 3 ulcers. As the HbA_{1c} values increased, so there was determined to be a statistically significant relationship with the development of PEDIS Grade 3 ulcer (P=0.003). In the comparison of the HbA_{1c} values according to the type of surgery performed, a weak relationship was determined at the rate of 26%, and it was determined that as the HbA_{1c} values increased, so there could be an increase in the amputation level.

CONCLUSION: The results of this study showed that as HbA_{1c} values at diagnosis increased in patients with diabetic foot; Wagner/PEDIS grades, disease severity, surgical extension, amputation level, and tissue loss increased. To reduce the severity of diabetic foot disease and prevent amputation, compliance with diabetic treatment and glycemic control should be increased.

Keywords: Diabetes mellitus; diabetic foot; disease severity; HbA_{1c}; surgical extension.

INTRODUCTION

The prevalence of diabetes mellitus (DM) is currently increasing; therefore, there has been an increase in the prevalence of diabetic foot, which is one of the most important complications of diabetes.[1-3] Each year DFUs develop in 9.1–26.1 million patients with diabetes worldwide, and the lifetime incidence of the diabetic foot has been reported to be 19%–34%.[2] The most important risk factors of diabetic foot are poor glycemic control, peripheral neuropathy, smoking, peripheral artery disease (PAD), foot deformities, callus, and a history of ulcers or amputation.[4]

Diabetic foot, which restricts movement capability, is characterized by ulcers, infection, and foot ischemia, and is the most common reason for hospitalization and amputation in

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patients with DM.[5] Moreover, 20% of DFUs do not recover within 1 year,[6] and even if wound healing is obtained, an average of 40% of cases are known to recur within 1 year.[2] Therefore, diabetic foot affects individuals in many aspects and increases health-care costs.[7] Following the development of diabetic foot, it is clear that clinical management, treatment of complicated patients, and sustainable protective care are difficult. Poor glycemic control adversely affects all phases of physiological wound healing, causing difficulty in wound healing and wounds to become chronic. Therefore, the standard care and treatment approach for diabetic foot patients aims to prevent infection and other complications by providing glycemic control.[8,9]

The hemoglobin A1c (HbA_{1c}) is the gold standard laboratory test that is used to evaluate glycemic control in patients with DM. In a normal healthy adult, 90% of hemoglobin is formed of Hemoglobin A. HbA_{1c} is a specific glycated hemoglobin originating from the covalent binding of glucose to the N-terminal valine of the hemoglobin β-chain.[10] Initially, this bond is reversible and can separate into glucose and hemoglobin, but with keto-amino binding, it gradually becomes an irreversible stable form.

HbA_{1c} allows to evaluate the quantitative index of glycemic control during the previous 8–12 weeks since the mean erythrocyte life span is approximately 120 days.[11-13] Diabetes Control and Complications Trial (DCCT; 1983–1993) and UK Prospective Diabetes Study (UKPDS; 1998) have clearly demonstrated the relationship between HbA_{1c} level and diabetic complications, such as peripheral neuropathy and PAD, which are significant risk factors in the formation of diabetic foot.[14-17] In individuals with diabetic foot wounds whose HbA_{1c} value is higher than >6.5%, the risk of lower extremity amputation is increased.[18-22] Therefore, one of the main goals in the management of diabetic foot patients is to reach appropriate glycemic targets and HbA_{1c} levels at all stages of clinical treatment. The aims of this study are to examine the relationship between HbA_{1c} values at first admission and diabetic foot severity according to the Wagner and perfusion, extent, depth, infection, sensation (PEDIS) grading systems and to investigate the relationship between the type of surgery performed and HbA_{1c} values of the patients with diabetic foot.

MATERIALS AND METHODS

This retrospective study included 301 consecutive patients who were diagnosed with diabetic foot in the general surgery diabetic foot clinic and were hospitalized for surgery between December 2019 and January 2021. Approval for the study was obtained from the local ethics committee before starting the study (Approval number: 2022/10 Date: November 22, 2022). The demographic data of the patients, the HbA_{1c} values at the time of presentation, the Wagner and PEDIS grades, and the surgical procedures applied were recorded and analyzed.

Statistical Analysis

Data obtained in the study were analyzed statistically using SPSS for Windows version 25.0 software (IBM Corp., Armonk, NY, USA). The conformity of the data to normal distribution was assessed with the Shapiro–Wilk W-test. Continuous variables were stated as mean ± standard deviation values and categorical values as number (n) and percentage (%). The relationships between continuous variables were evaluated with Pearson's correlation analysis and relationships between qualitative variables with Somer's D coefficient and the Phi–Cramer's analysis method. An error level of 0.05 was determined for all analyses.

RESULTS

Three hundred and one individuals with diagnosed with diabetic foot and hospitalized for surgical treatment were evaluated. Two hundred and thirty one (76.7%) of the patients were male, 70 (23.3%) were female, and the mean age was 62.18±10.29 years. The mean duration of diabetes in the patients was 12.29 (2–32) years.

According to the international DFU classification systems, 78.1% of the DFUs at the time of presentation were evaluated as Wagner Grade 4, and 69.8% as PEDIS Grade 3. The patients were separated into 3 groups for analysis according to the HbA_{1c} values at the time of presentation, as 6.5%–8%,

Table 1. Characteristics of diabetic foot cases and surgical procedures performed

	n	%
Wagner classification (%)		
Grade 1	4	1.3
Grade 2	28	9.3
Grade 3	34	11.3
Grade 4	235	78.1
PEDIS classification (%)		
Grade 2	81	26.9
Grade 3	210	69.8
Grade 4	10	3.3
HbA1c values (%)		
6.5–8	74	24.6
8.1–10	93	30.9
≥10.1	134	44.5
Type of surgical procedures (%)		
Debridement	22	7.3
Minor amputation	96	31.9
Minor amputation and debridement	159	52.8
Midfoot amputation	24	8.0
Total (%)	301	100

Table 2. Analysis of diabetic foot ulcer classifications and surgical procedure according to HbA1c groups

Characteristics	HbA1c groups			P
	6.5%–8%	8%–10%	↑10%	
Wagner classification (n)				
Grade 1	1	3	0	0.037[d]
Grade 2	7	12	9	
Grade 3	6	19	9	
Grade 4	60	59	116	
PEDIS classification (n)				
Grade 2	2	32	25	0.003[d]
Grade 3	4	57	103	
Grade 4	5	4	6	
Surgical procedure (n)				
Debridement	7	8	7	
Minor amputation	30	34	32	
Minor amputation and debridement	26	45	88	0.002χ^2
Midfoot amputation	11	6	7	

[d]Somer's D test; χ^2Pearson's Chi-square test.

8.1%–10%, and ≥10.1%. Almost half of the patients had HbA_{1c} level ≥10.1%.

When the patients were classified according to the surgery performed, minor amputation together with debridement was determined to be the most frequently applied (52.8%). The data are presented in Table 1.

We found a 90% statistically significant correlation between HbA_{1c} values ≥10.1% and the development of Wagner Grade 4 DFUs (P=0.037).

A strong statistically significant relationship at the rate of 85% was determined between HbA_{1c} values of ≥10.1% and the development of PEDIS Grade 3 ulcers. As the HbA_{1c} values increased, so there was determined to be a statistically significant relationship with the development of PEDIS Grade 3 ulcer (P=0.003).

In the comparison of the HbA_{1c} values according to the surgical procedure performed, a weak relationship was determined at the rate of 26%, and it was determined using the Phi–Cramer's analysis method that as the HbA_{1c} values increased, so there could be an increase in the level of surgical amputation (P=0.002). The results are presented in Table 2.

DISCUSSION

In our study, we found that HbA_{1c} values ≥10.1% in a large population of Type 2 DM hospitalized with diabetic foot were strongly correlated with Wagner Type 4 and PEDIS Stage 3, which are high degrees for the diabetic foot. It was determined that as the HbA_{1c} level increased, the level of amputation and tissue loss increased, threatening the functional foot health of the patients.

In the management of diabetes and diabetic foot, monitor long-term glycemic control, predict the risk of the development of complications, planning treatment, and evaluate the quality of diabetic care is primarily based on HbA_{1c} measurement. Previous long-term clinical studies have shown a linear relationship between serum glucose measurements and mean HbA_{1c} values, and very strong correlations between HbA_{1c} levels and the risks of complications.[10,17,23,24]

As with all other complications, studies have shown that there is a strong association between elevated HbA_{1c} levels and the risk developing of DFUs. HbA_{1c} is an independent risk factor for the development of DFUs.[25] Similarly, in a meta-analysis published by Tang et al., HbA_{1c} level was shown to be one of the factors predicting the development of DFU.[26]

The results of the present study revealed a significant correlation between the high HbA_{1c} values on presentation with the severity of diabetic foot, the surgical procedures applied, and the level of tissue loss present in the patients with diabetic foot. A meta-analysis involving 60 observational studies and 12,604 diabetic foot patients, suggest that A1c levels ≥8% and fasting glucose levels ≥126 mg/dL are associated with an increased likelihood of lower extremity amputation in patients with diabetic foot.[27] A meta-analysis from China revealed that increasing HbA_{1c} level increases the risk of amputation.[28]

In a meta-analysis that evaluated 11 studies of HbA_{1c} values in patients with diabetic foot, 43,566 patients were separated

into two groups of those on whom lower extremity amputation was and was not performed. The HbA_{1c} values were determined to be 8.3%–12.5% in patients who underwent lower extremity amputation.[18]

Similarly, in a cohort study investigating risk factors for transmetatarsal amputation failure in people with diabetes, it was shown that HbA_{1c} is the most important factor predicting the success of amputation.[29] In a meta-analysis by Zhou et al., which included 6 studies evaluating 109,933 patients with DM, there was reported to be a significant relationship between HbA_{1c} and the risk of amputation, and a mean increase of 1% in the HbA_{1c} value increased the probability of amputation 1.229-fold.[18] It has been stated prominently in the literature that poor glycemic control can increase the percentage of minor and major amputations.[30] In the present study, when the HbA1c value increased this predicted that the surgical amputation level could increase.

This finding supports the importance of lowering HbA_{1c} levels to reduce the amputation rates in patients with diabetes and 1% decrease in HbA_{1c} results in a 21% of reduction in all diabetic complications.[31,32] Similar to our results, Shatnawi et al. found that increased HbA_{1c} ≥8% level and also diabetes duration of ≥15 years, insulin therapy was an independent predictive factor for major lower extremity amputation.[33]

The HbA_{1c} value gives long-term information about the patient's glycemic control. The increased oxidative stress products of glycosylation formed together with hyperglycemia lead to microvascular and macrovascular complications in patients with diabetes. The changes related to hyperglycemia and glucose metabolism in patients with DFUs lead to the condition known as PAD, and the development of atherosclerosis together with endothelial damage, hyperlipidemia, increased viscosity, and thrombocyte activity. It has been reported that PAD, in other words, atherosclerotic obstructive disease, is present in 30%–78% of patients with DFUs.[34,35] A 1% increase in glycated hemoglobin increases the PAD risk by 28% and the incidence of PAD as an independent risk factor is associated with the duration of diabetes.[36] Vascular failure alone does not lead to ulceration but insufficient perfusion prevents ulcer healing, lays the ground for tissue necrosis, and prevents the clearing of infection.

The clinical status of DFUs can vary from uncomplicated cellulitis to limb and/or life-threatening necrotizing fasciitis. Poor glycemic control leads to immunological dysfunction with impaired leukocyte activity and complementary functions, and facilitates the development of invasive tissue infection. By creating oxidative stress in nerve cells, hyperglycemia leads to neuropathy, which affects sensory, motor, and autonomous nerves.[37]

In terms of the development of diabetic complications, a patient population with an optimal HbA_{1c} goal of <7% is encountered in large series at low rates such as 25.8% and 11.2%.[38] In our patient cohort requiring surgical treatment, the targeted HbA_{1c} level at diagnosis was present in only 24.6% of patients, indicating that we were attempting to treat a group without glucose control. Unfortunately, our patient group represents a high-risk group for the development of DFUs based on their characteristics.

The Wagner classification system, which evaluates ulcer depth and bone involvement, is helpful in the prediction of potential outcomes and is usually used to determine the appropriate treatment and care plan. The vast majority of the diabetic feet in the present study were Wagner Grade 4, which corresponds to localized gangrene in the forefoot or heel section. There was determined to be a strong correlation between increased HbA_{1c} values and the development of Wagner Grade 4 diabetic foot. Farooque et al. evaluated the correlation between the Wagner grading system and HbA_{1c} values. The mean HbA_{1c} value of the diabetic feet included in the study was reported to be 9.07%±1.65%, and >8.5% in the Wagner Grade 4 and 5 patients, and 59.08% of the diabetic feet were determined to be ≥Wagner Grade 4. One of the significant results of that study was that there was a linear relationship between the HbA_{1c} values and Wagner grades.[39] Nomograms for reamputation risk and the risk of below-ankle amputations have been identified to be consistent with our study, in which HbA_{1c} was identified as an important parameter.[39]

The aim of diabetic foot surgery is to provide a functional foot, and heel protective procedures and a wide foot surface area are attempted to be provided. In our study, it was shown that as the Wagner classification increased in patients who required below-knee amputation at diagnosis, the foot surface area decreased inversely with surgical width.

In the present study, analysis was made of a consecutive patient population that had to be hospitalized for treatment and required surgery. The patient group with no requirement for surgery was kept under outpatient follow-up and was not included in the research. Lu et al. reported the frequency of Wagner Grade 4 patients at 50.9% in their patients who underwent minor amputation.[40] Compared with the literature, the rate of 78.1% Wagner Grade 4 cases was high in our present study.

The basic reasons for advanced Wagner grades in diabetic foot are that strict glycemic control cannot be obtained and the associated high HbA_{1c} values. Increasing HbA_{1c} values can lead to the emergence of extensive tissue defects on the basis of neuropathic and vascular pathologies. In patients with diabetes who do not comply with foot care and diabetic treatment and follow-up, the development of advanced-grade diabetic foot which will cause extensive tissue loss is inevitable.

The vast majority of the diabetic feet in the present study were of moderate severity infection, threatening the extremity. In a study published in 2018 on the subject of glycemic control and infection risk in patients with Type 1 and Type 2 diabetes, it was concluded that there was a strong correlation between poor glycemic control and severe infections and that

HbA_{1c} values were a strong predictor for the development of infection.[41] In patients with poor glycemic control, infection is a short-term poor outcome of diabetic foot.[21]

The present study results showed an extremely strong correlation of HbA_{1c} ≥10% with the development of extremity-threatening PEDIS Grade 3 ulcers. Furthermore, we showed higher HbA_{1c} level increases the severity of the disease and tissue loss consistent with the literature. It is known that higher HbA_{1c} levels at clinical visits cause systemic inflammatory response syndrome (SIRS) development, and the presence of SIRS is a limb- and life-threatening condition for patients with DFU.[41,42] In patients with poorly controlled DM, the duration of antibiotic use is prolonged due to the increase in the PEDIS stage. The relationship between HbA_{1c} level and bacterial load is thought to be one of the reasons that prolong this period.[43]

CONCLUSION

Our findings showed that as HbA_{1c} values increase in patients with diabetic foot, Wagner and PEDIS grades increase, and tissue loss increases by increasing the severity of the disease and the level of amputation. In addition, an increase in surgical amputation borders predicts an increase in tissue loss. To reduce disease severity in patients with diabetic foot and avoid limb loss, appropriate evaluation of patients diagnosed with diabetes, the development of education and care models, and the early identification of high-risk groups are extremely important. With patient and family-centered care and follow-up models, precautions should be taken to prevent the development of diabetic foot, informing patients about the relationship between glycemic control and DFU, and improving long-term glycemic control.

Ethics Committee Approval: This study was approved by the University of Health Sciences Gulhane Research and Training Hospital Research Ethics Committee (Date: 22.11.2022, Decision No: 2022-345).

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Conflict of Interest: None declared.

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ORİJİNAL ÇALIŞMA - *ÖZ*

Diyabetik ayak hastalarında yüksek HbA_{1c} düzeyi ile hastalık şiddeti ve cerrahi seviye ilişkisi

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AMAÇ: Diyabetik ayak hastalarında standart tedavi ve bakım yaklaşımında özellikle hücresel bağışıklık, enfeksiyon ve diğer komplikasyonların ortaya çıkmasını sınırlandırmak ve yara iyileşmesini sağlamak için glukoz ve HbA_{1c} seviyesinin optimum düzeyde tutulması öncelikle önemsenmektedir.

GEREÇ VE YÖNTEM: Bu araştırma, genel cerrahi diyabetik ayak kliniğinde, diyabetik ayak tanısıyla servis yatışı yapılarak cerrahi uygulanan ardışık 301 hasta ile yürütülmüştür. Hastalara ait HbA_{1c} değerleri ile WAGNER ve PEDİS evreleri ile yapılan cerrahi işlemler arasındaki ilişki analiz edildi ve tedavi sonuçları değerlendirildi.

BULGULAR: HbA_{1c} değerleri %10.1 ve üzeri olanlar ile, Wagner evre 4 diyabetik ayak yara gelişimi arasında istatistiksel olarak %90'lık anlamlı bir ilişki olduğu saptandı (p=0.037). HbA_{1c} %10 ve üzeri olanlar ile PEDIS evre 3 yara gelişmesi arasında %85 oranında istatistiksel olarak kuvvetli bir ilişki olduğu saptandı. HbA_{1c} değerleri arttıkça, PEDIS evre 3 yara oluşumu arasında istatistiksel olarak anlamlı bir ilişki olduğu analiz edilmiştir (p=0.003). HbA_{1c} değerleri ile olgulara uygulanan cerrahi operasyonlar karşılaştırıldığında istatistiki olarak %26 oranında kuvvetli olmayan bir ilişki olduğu ve HbA_{1c} değerleri arttıkça cerrahi amputasyon seviyesinin artabileceği saptandı.

SONUÇ: Bu araştırmanın sonuçları, diyabetik ayaklarda HbA_{1c} değerleri yükseldikçe, Wagner ve PEDIS evrelerinin artacağı ve ilişkili olarak hastalık şiddetinin artacağı yönündedir. Yanı sıra cerrahi amputasyon sınırlarının artmasıyla doku kaybının artabileceği öngörülmektedir. Diyabetik ayak hastalık şiddetinin düşürülmesi ve uzuv kaybının önüne geçilebilmesi için diyabet tedavi ve glisemik kontrol uyumunun arttırılması gerekmektedir.

Anahtar sözcükler: Cerrahi seviye; diyabetes mellitus; diyabetik ayak; HbA_{1c}; hastalık şiddeti.

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