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Original Article

Evaluation of Relationship between Serum Hemoglobin A1C Level and Severity of Diabetic Foot Ulcers Based on Wagner Criteria

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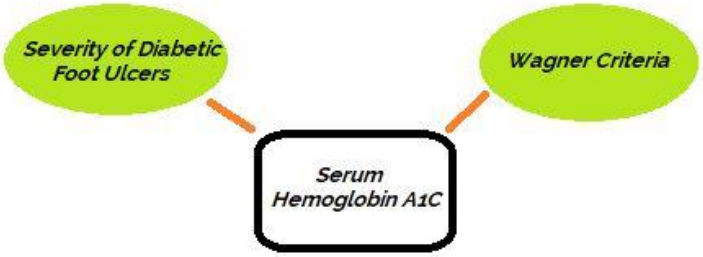
ABSTRACT

Introduction: One of the important risk factors for diabetic patients, including foot ulcers, is lack of blood sugar control, the standard criterion for which in the long run is the HbA1C measurement. Therefore, we examined the relationship between serum hemoglobin A1C levels and severity of diabetic foot ulcers according to Wagner criteria.
Materials and methods: This is a descriptive cross-sectional study. The target population was diabetic patients referred to the hospital, who were admitted to the infectious ward due to diabetic foot ulcers. Hemoglobin A1C levels were determined in all subjects. The severity of diabetic foot ulcers was then assessed according to Wagner criteria. Data analysis was performed using SPSS software version 26.
Results: In this study, 84 patients were included in the study, of whom 39 were female (46.4%) and 45 were male (53.6%). Out of 84 patients, 2 (2.4%) had grade 1 Wagner, followed by 10 (11.9%) grade 2, 24 (28.6%) grade 3, 35 (41.7%) grade 4, and 13 (15.5%) grade 5. The mean HbA1c of patients was 9.24±1.87. Its mean in grades 1, 2, 3, 4, 5, and 6 were 7.35 ± 0.35, 8.38 ±1.072, 8.73±1.12, 9.06 ±1.24 and 11.64 ± 2.93%, respectively. Elevated HbA1c was significantly associated with males (P = 0.038) and insulin use (P = 0.038), while elevated HbA1c was not significantly associated with age, duration of diabetes, underlying disease, and BMI (P> 0.05).
Conclusion: HbA1c level is a good criterion for evaluating the ulcers incidence and predicting the progression of diabetic foot ulcers in patients. By controlling HbA1c in the normal range and observing hygienic conditions, the occurrence and progression of diabetic foot ulcers can be prevented.

GRAPHICAL ABSTRACT



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Introduction

Diabetes as an endocrine disease is one of the most important and common health problems in the community that its prevalence in Iran is about 5.1 to 5.8% based on available statistics [1]. It causes complications such as ischemic heart disease, hypertension, retinopathy, neuropathy, nephropathy, and foot ulcers, and also is responsible for 4 million deaths per year and 9% of all deaths worldwide. The prevalence of diabetic foot ulcers is about 15-20% and counts for 85% of non-traumatic lower limb amputations [2]. Patients with this metabolic disease usually have a reduced life quality due to their numerous physical and psychological problems, so the diagnosis and treatment of this disease is important [3]. One of the major complications of diabetes is neuropathy followed by diabetic foot. The clinical presentation of diabetic neuropathy has a wide range. In both groups, the sensory-motor and peripheral nerves as well as their autonomic nerves are involved. Peripheral nerve involvement, together with peripheral vascular disease in the form of micro- or macroangiopathy predisposes a person to ulcers and infections of the legs [4]. Risk factors for foot ulcers are divided into two groups based on controllability, which include: (i) External factors: minor and thermal trauma, smoking and alcohol consumption, inadequate blood sugar control, obesity, and lack of patient cooperation and (ii) Internal factors: male gender, neuropathy, vasculopathy, immunopathy, age, duration of diabetes, and previous history of foot ulcers [5].

Diabetic foot ulcers can cause amputation in 2.1 to 13.7% of diabetic patients and is one of the most common causes of amputation in the world, while it is easily preventable [6, 7]. Of course, today effective treatments, which are mainly conservative, have been proposed for this disease [8-10] to prevent the dimensions of the disease and its progression and the need for amputation, thus resulting in a decreased economic loss caused by diabetes and wound complications [11] and improved their quality of life [12]. Of course, as mentioned, prevention can lead to better outcome in patients.

One of the most important methods of prevention in addition to educate diabetic patients for foot care is blood sugar control. Glycosylated Hemoglobin (HbA1C), which shows blood sugar levels over the past 8 to 12 weeks, is the standard for long-term glycemic control [13-16]. To investigate this issue about the severity of diabetic foot ulcers, we aimed to examine the relationship between serum hemoglobin A1C level and the severity of diabetic foot ulcers based on Wanger criteria in patients.

Materials and Methods

This descriptive cross-sectional study was performed on diabetic patients referred to Besat Hospital, Tehran, who were admitted to the infectious ward between 2019 and 2020 due to diabetic foot ulcers. Patients with inclusion and exclusion criteria were included in the study. Inclusion criteria were: having diabetic foot ulcer and informed consent. Exclusion criteria included: having other comorbidities including atherosclerotic diseases, neuropathic diseases, history of fracture or deformity in the lower extremities, and lack of informed consent.

Sample size

Concerning α = 0.05, d = 0.1, and P-value of 0.3, the sample size was calculated using the following formula. According to [17] in which 26% of diabetic patients had the highest severity of diabetic foot ulcers and the need for lower limb amputation, 84 patients were included in the study.

$$\frac{\left(Z1-\frac{a}{2}\right)2P(1-p)}{d2}$$

Z= 1.96 Attrition=0.1 N= 84

Procedure

Initially, demographic information including age, sex, BMI, smoking, presence of underlying diseases, type, and duration of diabetes were recorded. Hemoglobin A1C levels were determined in all subjects, and then the severity of diabetic foot ulcer was evaluated according to Wagner criteria, which includes six degrees,

including degree 0 (healthy skin), degree 1 (superficial wound), degree 2 (deep wound to tendon, bone or joint), degree 3 (deep wound with Abscess or osteomyelitis), grade 4 (frontal gangrene), and grade five (foot gangrene) were evaluated.

Data analysis

The frequency table was used to describe the qualitative variables and the mean and standard deviation were used to describe the quantitative variables. T-test and Chi-square tests were used to analyze the data. ANOVA was applied to compare the mean of a quantitative trait. Data analysis was performed using SPSS software version 26. A P-value of 0.05 was considered as statistically significant.

Ethical considerations

A written letter of introduction was received from university officials for the research centers. The purpose of the study was described for all research units and written consent was obtained from them. The information of all patients was kept confidential by the project manager. In all stages of the research, all ethical declarations of Helsinki and Ethics Research Committee of the University of Medical Sciences were considered. The study was carried out after approval by the Research Council of Medical School.

Results and Discussion

In this study, 84 patients were included in the study, of whom 39 were female (46.4%) and 45 were male (53.6%). The age distribution of patients was 38-71 with a mean of 53.14 ±9.90 years old. The mean age was 53.96 ±10.66 in men and 52.21 ± 8.97 in women. HbA1C levels of patients were divided into 4 groups including group 1: ≤ 7.5, group 2: 8.5 - 7.6, group 3: 9.5 - 8.6, and group 4 > 9.6. Of these, 8 patients (9.5%) had a HbA1C ≤7.5, followed by HbA1C between 7.6 to 8.5 (25 patients; 29.8%), HbA1C between 8.6 to 9.5 (27 patients; 32.1%) and HbA1C > 9.6 (24 patients; 28.6%). 60.7% of patients had HbA1C above 8.6. The mean total HbA1C of patients (lowest 6.5% and highest 18%) was 9.24 ±1.87. This rate was 7.55 ± 0.35 in patients with grade 1, followed by 8.38 ±1.07 for grade 2, 8.73 ±1.12 for grade 3, 9.06 ±1.24 for grade 4, and 11.64 ±2.93 for grade 5.

A statistically significant relationship was observed between the increase in A1C and the increase in the severity of Wagner involvement (P= 0.000), which increased the A1C amount led to an increase in Wagner grade.

In terms of the relationship between A1C distribution and Wagner involvement, in Wagner grade 5 most patients (76.92%) had A1C above 9.6. In Grade 4 Wagner, which had the highest number of patients, the diversity of HbA1C groups was higher than other groups, but most of the patients in this group (71.43%) had HbA1C between 7.6 and 9.5. With the increase of Wagner grade, the A1C level of patients also increased so that the A1C level less than 8.6 in grade 1 to 5 of Wagner decreased by 100%, 60%, 45.83%, 37.14%, and 7.69%, respectively.

According to the statistical analysis, a significant relationship was observed between the increase of Wagner grade and the increase of HbA1C in patients (P = 0.014). As the Wagner grade increases, the HbA1C spectra also increase and replace the lower spectra (HbA1C<8.6), so that HbA1C reached its highest level of more than 9.6 in grade 5.

Table 1 examines the relationship between Wagner age and grade, which shows a statistically significant relationship between age and Wagner involvement (P = 0.012).

In terms of sex and Wagner grade relationship, 39 were female and 45 were male. The mean Wagner in men was 4.46 ± 0.29 and in women was 2.72±0.69. A statistically significant relationship was found between males and the rate of Wagner involvement in patients (P = 0.000).

The relationship between the distribution of the underlying disease was examined in Table 2.

Our findings showed that 27 patients had diabetes, followed by hypertension (23 patients; 27.4%), hypertension (16 patients; 19%), and the presence of all three diseases (18 patients; 21.4%). There was no statistically significant relationship between the presence of the underlying disease and grade of Wagner involvement (P = 0.312).

Table 1: Relationship between age and Wagner grade

N		The Maximum	The Minimum	Mean
1	2	55.50±19.092	42	69
2	10	55.30±7.181	41	67
3	24	51.38±9.193	39	71
4	35	50.69±9.937	38	71
5	13	61.00±7.583	40	67
Total	84	53.14±9.673	38	71

Table 2: Correlation of underlying disease distribution

	Cumulative Percent	Valid Percent	Percent	Frequency
Non	27	32.1	32.1	32.1
HTN	23	27.4	27.4	59.5
HLP	16	19.0	19.0	78.6
MIX	18	21.4	21.4	100.0
Total	84	100.0	100.0	

Table 3 presents the distribution and relationship of smoking distribution with Wagner grade, where our data showed that 47 of 84 patients were smokers. The distribution of smoking in different Wagner grades was almost the same and was about 50 to 60%. Therefore, no statistically significant relationship was found between smoking and Wagner's involvement of patients (P = 0.523).

The distribution and relationship between BMI and Wagner grade are listed in Table 4. The BMI of patients was between 21 and 36 with a mean of 4.61 ± 29.10. The highest mean was in grade 5 of Wagner (31.54) and the lowest was in grade 1. There was no statistically significant relationship between BMI and patients' Wagner grade (P = 0.072). According to the results, it can be seen that there are not many changes in the BMI of different Wagner grades with each other, but there was an increasing trend.

Table 5 provides the relationship between the duration of diabetes and Wagner's involvement. The mean duration of diabetes was 10.73 ± 7.75 years, which showed an increasing trend with the increase of Wagner grade from 8.5 years in grade 1 to 13 years in grade 5. Although the duration of diabetes was directly associated with Wagner grade, but higher Wagner grades had a longer duration of disease. However, no statistically significant relationship was found between the two parameters (P= 0.75).

Table 3: Distribution and relationship of smoking distribution with Wagner grade

Wagner		1	2	3	4	5	Total
Smoking	No	1	7	10	14	5	37
	Yes	1	3	14	21	8	47
Total		2	10	24	35	13	84

Table 4: Dispersion distribution and relationship between BMI and Wagner grade

Wagner	N	Mean BMI	Std. Deviation	Std. Error	95% Confidence Interval for Mean		The Maximum	The Minimum
					Lower Bound	Upper Bound		
1	2	26.00	5.657	4.000	-24.82	76.82	22	30
2	10	26.30	3.199	1.012	24.01	28.59	22	32
3	24	29.50	4.934	1.007	27.42	31.58	21	36
4	35	28.89	4.626	0.782	27.30	30.47	21	36
5	13	31.54	3.821	1.060	29.23	33.85	23	36
Total	84	29.10	4.614	0.503	28.09	30.10	21	36

Table 5: Relationship between duration of diabetes and Wagner involvement

Wagner	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		The Minimum	The Maximum
					Lower Bound	Upper Bound		
1	2	8.50	6.364	4.500	-48.68	65.68	4	13
2	10	9.80	6.408	2.026	5.22	14.38	3	25
3	24	9.75	7.514	1.534	6.58	12.92	1	30
4	35	10.94	6.911	1.168	8.57	13.32	2	31
5	13	13.00	10.083	2.797	6.91	19.09	2	40
Total	84	10.73	7.495	0.818	9.10	12.35	1	40

A total of 33.3% of patients took insulin. No patients in grade 1 used insulin (0%), followed by 2 patients (20%) with grade 2, 6 patients (25%) with grade 3, 11 patients (31.4%) with grade 4, and 9 patients (69.2%) with grade 5. Increased insulin consumption was significantly associated with increased Wagner grade (P = 0.038) (Table 6).

One of the most important risk factors for complications of diabetes, including foot ulcers, is lack of blood sugar control, the standard criterion for which is long term measurement of HbA1C. Previous studies have shown that if the HbA1C level is increased by 2%, the risk of ulcers increases 1.6 times and the chance of amputation increases 1.5 times [18, 19]. Umar Farooque *et al.* showed that the older age, male gender, longer duration of DM, increased HbA1c, and previously existing foot abnormalities in diabetic patients has the risk factors of diabetic foot. They indicated the HbA1c increases the higher grades of Wagner classification of diabetic foot [20].

Therefore, the aim of this study was to evaluate the relationship between HbA1C and the severity of diabetic foot ulcers by Wagner criterion in predicting wound prognosis. In this study, 53.6% of patients were male and the mean Wagner was 4.29± 0.46 in men and 2.72± 0.69 in women which showed a significant difference (P = 0.000). The Farooque study also identified male gender as a risk factor for ulcers and exacerbation of Wagner involvement [17], which may be due to men's increased activity and use of their legs, highlighting the importance of HbA1C follow-up and occupational health education in diabetic men. The results of mentioned study were consistent with the present study.

Many studies have evaluated the association of HbA1C levels with the chance of amputation. Arya showed that lower extremity ulcers or gangrene were more common in diabetic patients with HbA1C above 7, and the chance of amputation increased significantly with an increase of HbA1C of more than 6%.

Table 6: Relationship between insulin use and Wagner involvement

			No	Yes	Total
Wagner	1	Count	2	0	2
		%within Wagner	100%	0%	100%
	2	Count	8	2	10
		%within Wagner	80%	20%	100%
	3	Count	18	6	24
		%within Wagner	75%	25%	100%
	4	Count	24	11	35
		%within Wagner	68.6%	31.4%	100%
	5	Count	4	9	13
		%within Wagner	30.8%	69.2%	100%
Total		Count	56	28	84
		%within Wagner	66.7%	33.3%	100%

The chance of amputation doubles with a 1% increase of HbA1C (HbA1C 6% compared to HbA1C less than 6%) [21]. These findings are consistent with the results of the present study. In addition, Hassan's study showed that strict control of HbA1C between 6 and 7.5% has preventive effects on the risk of amputation (Risk Ratio = 0.45-0.94) [22].

By examining the results of this study, it seems that following diabetic foot ulcers with HbA1C and keeping HbA1C in normal range can reduce the complications and severity of Wagner involvement in diabetic patients. Newhall study indicated the benefits of the HbA1C check in preventing amputation. Aforementioned study reported that the amputation rate decreased by 50%, when the HbA1C follow-up population increased from 74% to 84% [23]. Frykberg found that male gender, a history of more than 10 years of diabetes, a previous history of foot ulcers, smoking, neuropathy, deformity of the foot; peripheral vascular disease and lack of HbA1C control were effective in causing foot ulcers [24]. This study is consistent with our findings.

Studies on the HbA1C association with the level of Wagner involvement in patients showed that an increase in HbA1C is associated with an increase in the severity of Wagner involvement. Farooque showed a direct linear relationship between the increase of HbA1C and the increase of Wagner grade. In this study, this issue was repeated with P-value of 0.000 and the mean HbA1C increased with the increase of Wagner engagement grade so that HbA1C in grade 1 Wagner increased from 7.55 ± 0.35 to 11.64 ± 2.93 in grade 5 Wagner.

HbA1C levels of <8.6 in grades 1 to 5 of Wagner decreased from 100%, 60%, 45.83%, 37.14% and 69%, respectively [17]. Ramani *et al.* reported that the mean HbA1C was 9.77 ± 2.34 in patients with non-ulcerative diabetes and 14.4±3.63 in patients with foot ulcers [25], showing a mean HbA1C higher than current study.

Conclusion

Regarding the direct relationship between increased HbA1c and Wagner grade, controlling HbA1c within the normal range and recommending hygienic foot care can reduce the incidence the incidence of diabetic foot ulcers and limb amputation. Further studies are needed to more accurately determine the effect of other variables on diabetic foot ulcers and their association with HbA1c. Because of controlling HbA1c in a precise range, patients' foot ulcer approach can be evaluated and predicted.

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Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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