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Research Article

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Risk Factors for Ulceration in Diabetes Mellitus in the Preventive Foot Clinic at the Medical Center for Diabetes, Obesity, and Specialties, During the Period January-April 2022.

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Abstract

Introduction: *Diabetes Mellitus is a conglomerate of metabolic alterations that chronically affect health. Neuropathy, previous ulcers, foot deformities, peripheral arterial disease, and chronic kidney disease are risk factors that predispose to the development of foot ulcers. It was carried out in order to determine risk factors for ulceration in people living with diabetes mellitus.*

Materials and methods: *Descriptive observational study of 233 people who attended the Preventive Foot consultation at the Diabetes, Obesity and Specialties Medical Center, during the period January-April 2022. Information collected through a questionnaire that reported age, sex, marital status, time of diagnosis of diabetes mellitus, history of ulcer, amputation, bone deformity, chronic renal failure, neuropathy and peripheral arterial disease.*

Results: *60% female, 40% male, 60% ≥ 62 years. 39.6% with diagnosis time ≥16 years, 65.2%-foot deformity, 12.8% previous ulcer, 5.1% previous amputation, 10.3% chronic renal failure, 36% peripheral neuropathy and 31.3% peripheral arterial disease. 47.6% presented a very low risk, 27.5% moderate, 15% high risk and 9% low. Association time of diagnosis and neuropathy chi2= 8.993, p= <0.029. Ulcer and amputation correlation rho=0.606, p=< .001.*

Discussion: *As risk factors predominated foot deformity, followed by diabetic neuropathy and peripheral arterial disease. With significant association between the time of diagnosis and neuropathy. With moderate direct proportional correlation between ulcer and previous amputation*

1. Introduction

Diabetes is a chronic disease that occurs when the pancreas no longer produces enough insulin or when the body cannot use it properly. Insulin is a hormone generated by the pancreas and is essential for glucose to enter the bloodstream and provide energy [1].

According to the International Diabetes Federation [1]. Type 1 Diabetes Mellitus (DM1) is more common during childhood and adolescence, although it can occur at any age. People with DM1 produce very little or no insulin, making them insulin-dependent, meaning they need to administer insulin permanently to maintain glucose levels within normal values. In addition, there is Type 2 diabetes mellitus (DM2), more common in adulthood, which accounts for 90% of all diabetes cases. The main treatment is based on a healthy lifestyle, physical activity, and a healthy diet. However, in the majority of cases, medication in the form of oral drugs and, occasionally, insulin administration is necessary to maintain and control blood glucose levels.

According to statistics published by the Centers for Disease Control and Prevention [2]. There are 34.2 million people with diabetes in the United States, 26.9 million diagnosed individuals, and 7.3 million undiagnosed individuals. Additionally, the number

of individuals at risk of developing the disease, also known as prediabetics, is estimated at 88 million adults over 18 years of age and 24.2 million individuals aged 64 years or older. Similarly, the International Diabetes Federation [1]. Estimates that 11.3% of global deaths are caused by diabetes and those approximately 4.2 million adults died from diabetes-related complications in 2019. Uncontrolled elevated levels of blood glucose can lead to damage in the nervous, circulatory, immune systems, and various major organs such as the eyes and kidneys. In addition to elevated blood glucose levels, age, gender, alcohol and tobacco consumption, high blood pressure, elevated triglycerides and cholesterol, and obesity are other factors that influence the development of Neuropathy [3].

Diabetes Mellitus is considered the most common cause of neuropathy, with over 50% of all diagnosed individuals presenting focal or diffuse damage to the nervous system [4]. The International Diabetes Federation [1]. Explains that the extremities, particularly the lower limbs, are the most affected area. Nerve damage in this area is called peripheral neuropathy and is characterized by pain, tingling, and loss of sensitivity. The loss of sensation, in particular, allows these injuries to occur without the person's awareness, predisposing them to severe infections and possible amputations. It has been shown that people with diabetes have a 25-fold higher risk of amputation compared to those without the disease.

Diabetic Foot (DF) is one of the most serious complications that negatively impact both individuals and their families. This is because partial or total amputations of the lower limbs are sometimes necessary, leading to significant psychological, social, and economic burdens [5]. According to the International Working Group on the Diabetic Foot (IWGDF), the main factors influencing the development of ulcers are peripheral neuropathy, mechanical stress, calluses, and peripheral arterial disease (PAD). Bone deformities, loss of protective sensation, peripheral arterial disease, previous ulcer or amputation, and end-stage renal disease are considered predictive factors for ulcer development [6]. Bone deformities are one of the most prevalent conditions, including hallux valgus or bunion, hammer toe, claw toe, mallet toe, flatfoot, cavus foot, among others. These deformities significantly increase the likelihood of foot injuries that may go unnoticed initially and develop into foot ulcers [7].

Likewise, peripheral arterial disease (PAD), most commonly caused by atherosclerosis, is present in up to 50% of people with diabetic foot ulcers. PAD is considered a significant risk factor for impaired ulcer healing and lower extremity amputation [6]. On the other hand, it has been demonstrated that an early diagnosis of Diabetes Mellitus accompanied by glycemic control influences the delayed onset of complications such as ulcers and, in turn, the risk of lower limb amputation. Similarly, a study published by Mayo Clinic [8]. Concluded that diabetes control and proper foot care contribute to ulcer prevention, resulting in a more than 50% reduction in lower limb amputation rates over the past 20 years. The purpose of this research is to identify ulceration risks in individuals living with diabetes mellitus who receive preventive foot care at the Center for Diabetes, Obesity, and Specialties (CEMDOE). Considering that prevention is a key factor when it comes to ulcers in people with diabetes, we aim to demonstrate that risk factor prevention and glycemic control are essential for patients with Diabetes Mellitus. In doing so, we seek to contribute to reducing the incidence of foot ulcers in individuals with Diabetes Mellitus

2. Materials & Methods

2.1 Context

This study was conducted with the purpose of determining ulceration risks in individuals with Diabetes Mellitus and, thus, identifying the risk factors that most affect the population. Currently, diabetes represents a socioeconomic and health problem; therefore, we seek to contribute to the prevention of future complications and raise awareness among both affected and unaffected individuals. The Center for Diabetes, Obesity, and Specialties (CEMDOE) was chosen as the study location because it is the leading diabetes center in the Dominican Republic in terms of technology for the diagnosis and treatment of foot conditions in people with diabetes. Additionally, it houses a range of professionals from different specialties for the integrated management of individuals attending the center. These strengths make it the ideal place to provide services to people with diabetic foot conditions.

2.2. Project Modality

This is a research project, as it aimed to study the risk factors for ulceration in individuals with Diabetes Mellitus, while respecting the processes inherent to scientific methodology, with the purpose of contributing to the prevention of future complications and raising awareness about this condition. Likewise, it seeks to contribute to the healthcare system of the Dominican Republic.

A questionnaire was used. The information was collected from the database of the Center for Diabetes, Obesity, and Specialties. Anonymously, meaning no personal patient data was used, the information was numbered to maintain data order. Subsequently, the data was tabulated to identify the risk factors for ulceration and classify the risk of ulceration within one year for the participants using the 2019 IWGDF Risk Stratification System, a publicly available guide intended for healthcare professionals involved in the care of individuals with diabetes.

3. Methods and Techniques

A questionnaire was used. The information was collected from the database of the Diabetes, Obesity, and Specialties Medical Center. Anonymously, meaning no personal patient data was used, the information was numbered to maintain data order. Subsequently, the data was tabulated to identify the risk factors for ulceration and classify the risk of ulceration within one year for the participants using the 2019 IWGDF Risk Stratification System, a publicly available guide intended for healthcare professionals involved in the care of people with diabetes. The questionnaire used for data collection consists of 11 questions divided into 2 sections. The first section consists of 3 questions regarding age, gender, and marital status. The second section contains 8 questions pertaining to personal history, such as the duration of Diabetes Mellitus diagnosis, previous occurrence of ulcers or amputations, bone deformities, chronic renal insufficiency, diabetic neuropathy, and peripheral arterial disease.

4. Ethical Considerations

With the intention of ensuring the safety of individuals who participated in this study, complying with the bioethical requirements of the Research Ethics Committee (CEI 2022-65) of the Dean's Office of Research and Innovation (DII) at Universidad Iberoamericana, the topic was submitted and upon its approval, the research project was carried out. To achieve this, participants completed an informed consent form, which explained that they were not obligated to participate in this study, that there were no physical or psychological risks associated with their participation, and that they could choose to withdraw from the study at any time. It was also specified that all information obtained through the questionnaire would be completely anonymous and confidential.

5. Population

Adults over 18 years old with Diabetes Mellitus who attend the Preventive Foot Consultation at the Diabetes, Obesity, and Specialties Medical Center (CEMDOE), during the period January-April 2022.

6. Sample

A total of 233 individuals over 18 years old with Diabetes Mellitus, who attended the Preventive Foot Clinic and met the inclusion criteria, will be surveyed until the deadline of our data collection period at the Diabetes, Obesity, and Specialties Medical Center (CEMDOE) during the January-April 2022 period. To determine the sample, the Raosoft calculator was used with a margin of error of 5%, a confidence interval of 95%, and a distribution margin of 50%.

Inclusion criteria: All individuals over 18 years of age with Diabetes Mellitus who attended the Preventive Foot Clinic at the Diabetes, Obesity, and Specialties Medical Center (CEMDOE), during the period January-April 2022, of both sexes, and older than 18 years.

Exclusion criteria: Individuals under 18 years of age, those with physical-motor disabilities, sensory disabilities, cognitive disabilities, mental illness, and pregnancy.

Results

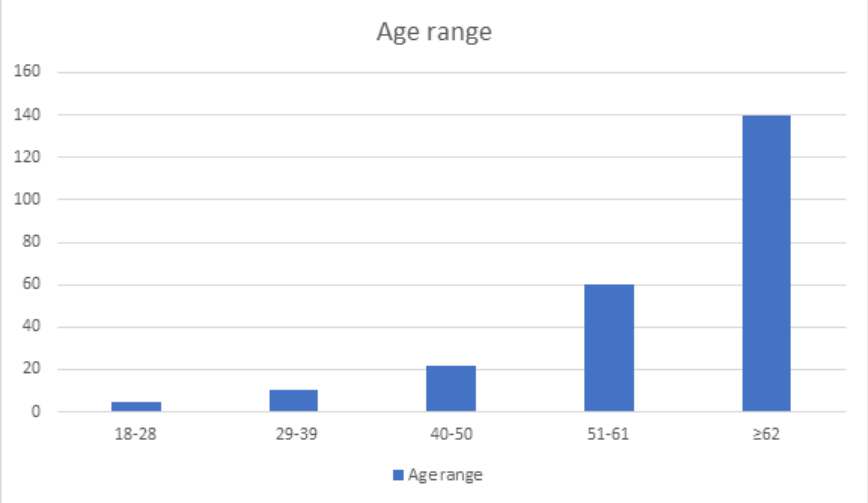

Figure 1: Age Distribution of Individuals with Diabetes Mellitus Who Attended Preventive Foot Consultation at the Medical Center for Diabetes, Obesity, and Specialties During the Period January-April 2022 (n=233).

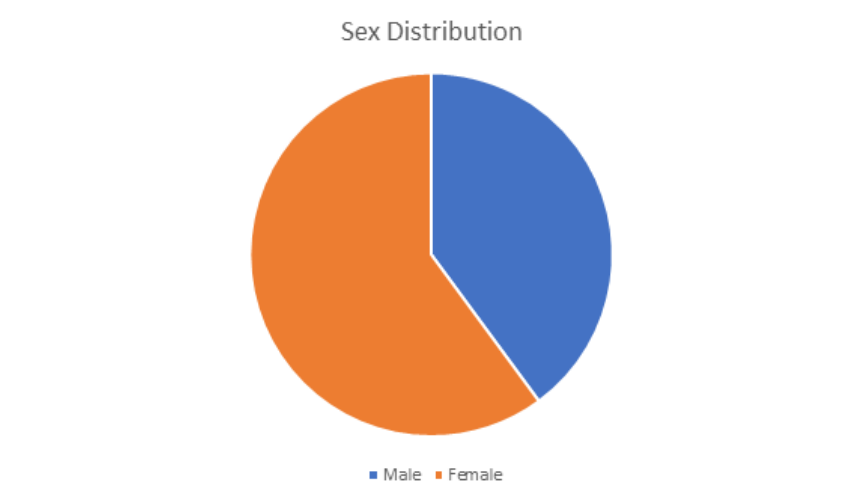

Figure 2: Distribution of Individuals with Diabetes Mellitus Who Attended Preventive Foot Consultation at the Center for Diabetes, Obesity, and Specialties, During the Period January-April 2022 (n=233).

Marital Status	Frequency	Percentage (%)	Valid Percentage
Single	96	41.202	48.980
Married	73	31.330	37.245
Concubinage	13	5.579	6.633
Widow	14	6.009	7.143
Divorced	37	15.880	
Total	233	100	100

Table 1: Marital Status Distribution of Individuals with Diabetes Mellitus Who Attended Preventive Foot Consultation at the Medical Center for Diabetes, Obesity, and Specialties during the Period of January to April 2022 (n=233)

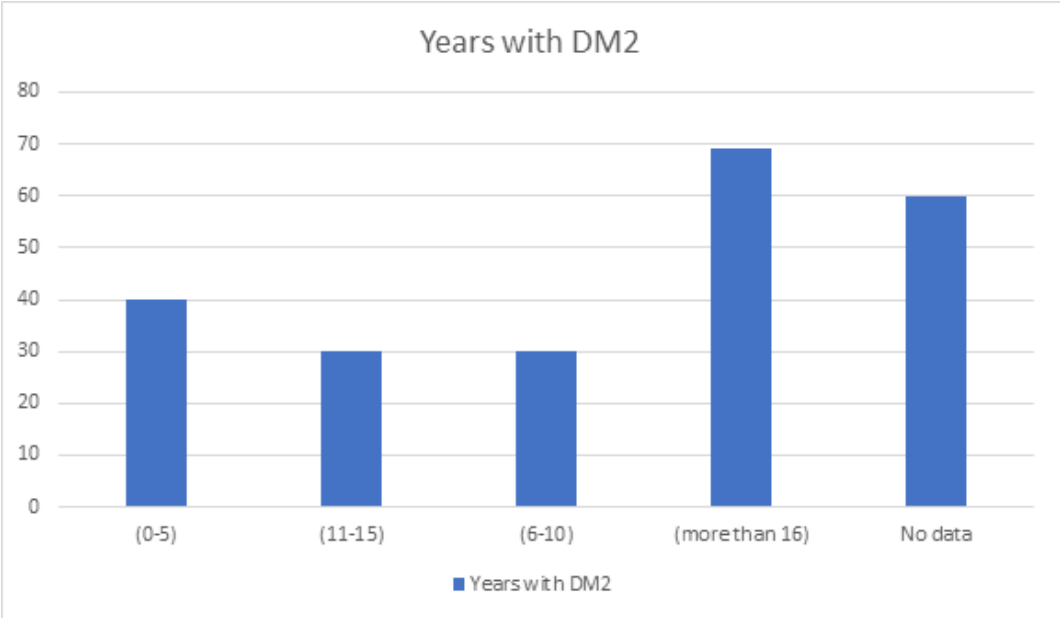

Figure 3: Distribution of Diagnosis Time for Individuals with Diabetes Mellitus Who Attended Preventive Foot Consultation at the Medical Center for Diabetes, Obesity, and Specialties During the Period January-April 2022 (n=233).

Previous Ulcer	Frequency	Percentage (%)
Yes	30	12.876
No	203	87.124
Total	233	100

Table 3: Distribution of the Previous Ulcer Variable for Individuals with Diabetes Mellitus Who Attended Preventive Foot Consultation at the Center For Diabetes, Obesity, and Specialties Medical Center During the Period January-April 2022 (n=233).

Previous Amputation	Frequency	Percentage (%)
Yes	12	5.150
No	221	94.850
Total	233	100

Table 4: Distribution of the Variable of Previous Amputation in Individuals with Diabetes Mellitus Who Attended the Preventive Foot Clinic at the Medical Center for Diabetes, Obesity, and Specialties During the Period January-April 2022 (n=233).

Foot Deformity	Frequency	Percentage (%)
Yes	152	65.236
No	81	34.764
Total	233	100

Table 5: Distribution of the Variable of Foot Deformity in Individuals With Diabetes Mellitus Who Attended the Preventive Foot Clinic at the Medical Center for Diabetes, Obesity, and Specialties During the Period January-April 2022 (N=233).

Chronic Kidney Disease	Frequency	Percentage (%)
Yes	24	10.3
No	209	89.7
Total	233	100

Table 6: Distribution of the Variable of Chronic Kidney Disease in Individuals with Diabetes Mellitus Who Attended the Preventive Foot Clinic at the Medical Center for Diabetes, Obesity, and Specialties During the Period January-April 2022 (n=233).

Neuropathy	Frequency	Percentage (%)
Yes	84	36.052
No	149	63.948
Total	233	100

Table 7: Distribution of the Variable of Neuropathy in Individuals with Diabetes Mellitus Who Attended the Preventive Foot Clinic at the Medical Center for Diabetes, Obesity, and Specialties During the Period January-April 2022 (n=233).

Peripheral artery disease	Frequency	Percentage (%)
Yes	84	36.052
No	149	63.948
Total	233	100

Table 8: Distribution of Peripheral Arterial Disease Variable for Individuals with Diabetes Mellitus Who Attended Preventive Foot Consultation at the Center for Diabetes, Obesity, and Specialties, During the Period January-April 2022 (n=233).

7. Discussion

In this study, data were collected from a total of 233 people living with Diabetes Mellitus to determine the risk factors for ulceration among those who attended the Preventive Foot Clinic at the Diabetes, Obesity, and Specialties Medical Center. When examining the distribution by sex, it was found that 60.1% (n=140) corresponded to females and 39.9% (n=93) to males. In the article titled "Evaluation of peripheral neuropathy and ulceration risk in diabetic patients according to the criteria of the International Working Group on the Diabetic Foot," published in the journal of the Latin American Hypertension Society, it was concluded that females were the most affected, representing 64% of the sample [4]. Similar results were found in the publication "Moderate prevalence of foot at risk of ulceration in type 2 diabetics according to IWGDF in the context of primary care," which studied 301 patients and concluded that 59.5% were female [9].

Regarding the marital status variable, it was found that 41.2% (n=96) were single, 31.3% (n=73) were married, 5.5% (n=13) were in a common-law relationship, and 6% (n=14) were widowed. No similar studies considering this variable were found. Regarding the analysis of the age variable, the age group with the highest prevalence was 62 years or older, accounting for 60.5% (n=69) of the participants. The percentages for the age ranges were as follows: 51-61 years, 23.6% (n=55); 40-50 years, 9.4% (n=22); 29-39 years and 18-28 years, both 5.2% (n=12); and 1.3% (n=3) for ages below 18. This is consistent with the article titled "Evaluation of peripheral neuropathy and ulceration risk in diabetic patients according to the criteria of the International Working Group on the Diabetic Foot," published in the journal of the Latin American Hypertension Society, where the most frequent ages were 61 to 75 years, accounting for 54% of the sample (Ramírez et al., 2019). Similarly, the study "Classification of the foot at risk of ulceration according to the IWGDF system and associated factors in type 2 diabetic patients from a Peruvian hospital" found that the average age was 60 years [10].

For the variable of time since diagnosis, the results showed that 39.7% (n=69) had been diagnosed for 16 years or more, followed by a range of 0-5 years at 23.6% (n=41), and 6-10 years and 11-15 years both at 18.4% (n=32). In similarity with the article titled "Risk factors for foot ulcers in diabetics attending a community rehabilitation service," the disease duration was found to be 12.8 years [11]. However, the publication in the Scielo Peru journal titled "Classification of the foot at risk of ulceration according to the IWGDF system and associated factors in type 2 diabetic patients from a Peruvian hospital" reported

a shorter time since diagnosis, where 55% of people had been diagnosed with diabetes mellitus for more than 5 years [10].

For the variable "diagnosis time," the results showed that 39.7% (n=69) had a diagnosis of the disease for 16 years or more, followed by a range of 0-5 years with 23.6% (n=41), and 6-10 years and 11-15 years, both obtaining 18.4% (n=32). Similarly, in the article titled "Risk factors for foot ulcers in diabetic patients attending a community rehabilitation service," the disease duration was reported as 12.8 years [11]. However, in the publication titled "Classification of the foot at risk of ulceration according to the IWGDF System and associated factors in patients with type 2 diabetes mellitus in a Peruvian hospital," the diagnosis time was shorter, with 55% of individuals having more than 5 years since the diagnosis of diabetes mellitus [10]. Regarding previous ulcers, 12.9% (n=30) reported having had a previous ulcer, while 87.1% (n=203) did not. Additionally, 5.2% (n=12) had undergone a previous amputation, and 65.2% (n=152) had a foot deformity. In contrast, the study "Risk factors associated with the development of ulcers in patients with Type 2 Diabetes Mellitus: Seven years of experience" found a 34.9% prevalence of ulcers. It is worth noting that this study evaluated 3,270 individuals over a 7-year period, yet we can still conclude that the majority of participants did not present an ulcer, similar to our study. Furthermore, 9.4% had undergone a previous amputation, and 30.5% had orthopedic abnormalities [12].

In contrast, the study "Classification of the foot at risk of ulceration according to the IWGDF System and associated factors in patients with type 2 diabetes mellitus in a Peruvian hospital," with a sample of 382 individuals that is more similar to our study, reported a 6.5% prevalence of previous ulcers or amputations and a 54.3% prevalence of bony deformities of the variable Peripheral Neuropathy, 36.1% (n=84) of individuals presented the condition. Similar results can be found in the medical journal Scielo Peru, in an article titled "Classification of foot ulceration risk according to the IWGDF system and associated factors in patients with type 2 diabetes mellitus from a Peruvian hospital," where 35.5% of individuals had Peripheral Neuropathy [10].
Regarding the variable Chronic Kidney Disease, it was found that 10.3% (n=24) of individuals had the condition, while 89.7% (n=209) did not. This is in comparison to an article published in the Nephrology journal titled "Chronic kidney disease in Spain: prevalence and related factors in individuals with diabetes mellitus over 64 years of age," which reported a prevalence of chronic kidney disease of 37.2% [13].

Regarding the analysis of Peripheral Arterial Disease, 31.3% (n=73) presented the condition. Comparing this with an article published in the Journal of the Argentine Society of Diabetes titled "Risk factors associated with the development of ulcers in patients with Type 2 Diabetes Mellitus: Seven years of experience," where 34.7% of individuals had vascular alterations [12]. Additionally, in the publication "Classification of foot ulceration risk according to the IWGDF system and associated factors in patients with type 2 diabetes mellitus from a Peruvian hospital," 39% of participants had Peripheral Arterial Disease. Analyzing the data to classify the risk of ulceration using the 2019 IWGDF Risk Stratification System, out of a total of 233 individuals, the results showed that 47.6% (n=111) had a very low risk of ulceration, 27.5% (n=64) had a moderate risk, 15% (n=35) had a high risk, and 9% had a low risk (n=23).

In an article published by the medical journal Scielo Peru titled "Classification of foot ulceration risk according to the IWGDF system and associated factors in patients with type 2 diabetes mellitus from a Peruvian hospital," 22% had a low risk, 8% had a moderate risk, 64% had a high risk, and 6.5% had a maximum risk [10]. In contrast to the article entitled "Evaluation of peripheral neuropathy and the risk of ulceration in diabetic patients according to the criteria of the International Working Group on Diabetic Foot" (34), where 74% of the individuals presented a high risk, 16% presented maximum risk, 5% presented low risk, and another 5% presented moderate risk [4]. However, 86.7% do not present any risk, 4% present a mild risk, and 9.3% present moderate risk [9]. Participants who presented ulcers have a 5.6 times higher likelihood of undergoing amputation than those who did not present ulcers, meaning that 12.9% have a higher likelihood of being amputated. Likewise, the null hypothesis is rejected, and it is established that there is a statistically significant association, OR = 5.6, p-value < .001.

Regarding the relationship between time of diagnosis and neuropathy, the null hypothesis is rejected, and it is established that there is a statistically significant association, Chi-square = 8.993, p-value < 0.029. For the other relationships, the null hypothesis is accepted, and it is established that there is no statistically significant relationship between the variables. Analyzing the effect size, it is established that the result is strong for the variables of previous ulcer and amputation, indicating a strong association between these variables, Cramer's V = 0.61. Similarly, for time of diagnosis and neuropathy, the result is strong, indicating a strong association between these variables, Cramer's V = 0.23. However, for the other relationships, the result is weak, although statistically significant, indicating a weak association between the variables.

8. Conclusion

In conclusion, multidisciplinary work is essential for the management of these patients. Therefore, having knowledge about the most predominant risk factors and predictors in the development of ulcers will help us reduce their occurrence and the associated complications. In this study, the majority of participants were female, aged 62 years or older, had a diabetes duration of 16 years or more, and there was a higher prevalence of unmarried patients. The risk factor that predominated the most was foot deformity, followed by diabetic neuropathy and peripheral artery disease. Participants who presented with ulcers have a 5.6 times higher likelihood of undergoing amputation than those who did not present ulcers. There is a statistically significant association between previous ulceration and amputation variables, as well as the time of diagnosis and neuropathy. For the variables of previous ulceration and amputation, it can be concluded that there is a moderately direct proportional correlation. Lastly, the risk of ulceration within one year was classified for patients who attended the Preventive Foot Consultation at the Center for Di-

abetes, Obesity, and Specialties (CEMDOE) during the period of January-April 2022. Guided by the IWGDF guidelines, it is concluded that the majority of participants presented a very low risk, followed by moderate, high, and low risk, respectively.

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