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ORIGINAL

Factors that impact in the answer of the ulcers from the diabetic foot to the Heberprot-P®

Factores que inciden en la respuesta de las úlceras del pie diabético al Heberprot-P®

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ABSTRACT

Introduction: the diabetes mellitus constitutes a problem of health to world scale for its growing incidence and for its complications, mainly associated to the vascular damage that you/they usually present, as the ulcer of diabetic foot that can take to the amputation and discapacidad.
Objective: to identify the factors that impact in the answer of the ulcers from the diabetic foot to the Heberprot-P® in patient belonging to the policlínico September 5, Consolation of the South, Pinegrove of the River, in the period of January 2022 and January of the 2024.
Method: he/she was carried out an observational, analytic, and traverse study. The universe was represented by all the diabetic patients (n=1875) belonging to the selected policlínico and the sample for those with ulcer of the diabetic foot, treaties with Heberprot-P®. (n=28). the theoretical, empiric and statistical methods were used.
Results: the patients prevailed with more than 70 years (64,2 %), feminine sex (65,3 %) and white color of the skin (71 %). The arterial hypertension (56,3 %) and the obesity (8,6 %) they are the observed pathological antecedents. The most frequent localization in the ulcers was the region metatarsiana (28,57 %), 60,7 % of these lesions healed before the 3 months. the time of cure of the lesion showed statistical relationship with the presence of obesity, tabaquismo and an inadequate feeding and the biggest age.
Conclusions: the age, obesity, the tabaquismo and the alimentary habits were factors that impacted in the answer of the ulcers from the diabetic foot to the Heberprot-P®.

Keywords: Diabetes Mellitus; Factors of Risk; Diabetic Foot; Heberprot-P®.

RESUMEN

Introducción: la diabetes mellitus constituye un problema de salud a escala mundial por su creciente incidencia y por sus complicaciones, principalmente asociadas al daño vascular que suelen presentarse, como la úlcera de pie diabético que puede llevar a la amputación y discapacidad.
Objetivo: identificar los factores que inciden en la respuesta de las úlceras del pie diabético al Heberprot-P® en pacientes pertenecientes al policlínico 5 de Septiembre, Consolación del Sur, Pinar del Río, en el período de enero 2022 y enero del 2024.
Método: se realizó un estudio observacional, analítico, y transversal. El universo estuvo representado por todos los pacientes diabéticos (n=1875) pertenecientes al policlínico seleccionado y la muestra por aquellos con úlcera del pie diabético, tratados con Heberprot-P®. (n=28). Se emplearon los métodos teóricos, empíricos y estadísticos.

Resultados: predominaron los pacientes con más de 70 años (64,2 %), sexo femenino (65,3 %) y color blanco de la piel (71 %). La hipertensión arterial (56,3 %) y la obesidad (8,6 %) son los antecedentes patológicos más observados. La localización más frecuente de las úlceras fue la región metatarsiana (28,57 %), el 60,7 % de estas lesiones sanaron antes de los 3 meses. el tiempo de curación de la lesión mostró relación estadística con la presencia de obesidad, tabaquismo y una alimentación inadecuada y la mayor edad.
Conclusiones: la edad, obesidad, el tabaquismo y los hábitos alimentarios fueron factores que incidieron en la respuesta de las úlceras del pie diabético al Heberprot-P®.

Palabras clave: Diabetes Mellitus; Factores de Riesgo; Pie Diabético; Heberprot-P®.

INTRODUCTION

Chronic non-communicable diseases (NCDs) are a major public health problem worldwide.[1] They represent the leading causes of morbidity and mortality among older adults in developed and developing countries, with hypertension and Diabetes Mellitus (DM) being the most common.[2,3]

DM is a syndrome of impaired carbohydrate, fat and protein metabolism caused by a lack of insulin secretion or decreased tissue sensitivity to insulin.[4]

There are two general types of diabetes mellitus. Type 1 Diabetes, also called insulin-dependent diabetes mellitus which is caused by a lack of insulin secretion and Type 2 Diabetes, also called non-insulin-dependent diabetes mellitus, which is initially due to a decreased sensitivity of target tissues to the metabolic effect of insulin. This reduced sensitivity to insulin is often referred to as insulin resistance.[4,5]

The International Diabetes Federation estimated a global prevalence of diabetes in adults aged 20-79 years in the year 2021 of 10,5 %, by 2030 it projects an increase to 11,3 % and by 2040 up to 12,2 %.[6]

The incidence of diabetes is increasing rapidly with estimates suggesting that this number will almost double by 2030. Diabetes mellitus occurs worldwide but is most common in developed countries. The greatest increase in prevalence in the near future is expected to occur in Asia, the Middle East and Africa, where there is likely to be a 50 % increase in diabetes in these parts of the world by 2030.[7]

According to official data from 2018 the prevalence of type 2 DM in Mexico was 10,3 %. Added to the above, it is estimated that the percentage of individuals with undiagnosed DM is just over 50 % highlighting the need for timely diagnosis that allows adequate care to delay potential sequelae of the disease at the individual, family and society in general.[8]

The prevalence rate in Cuba during 2022 was 66,5 per thousand inhabitants, and in Pinar del Río, this was 68,5 per thousand inhabitants, it was the sixth province with the highest prevalence.[9]

This disease is considered a worldwide health problem. This is due to its increasing and high incidence and prevalence rates. At the same time it constitutes an important cause of morbidity and mortality in the adult population and a risk factor for the appearance of other diseases of vascular origin, which are among the first causes of death in the world and in Cuba.[10]

Diabetic patients usually present complications, which generally appear with the years of evolution, especially in patients without an adequate metabolic control. Long-term complications are mainly vascular and very varied and are due, at least in part, to the chronic elevation of glucose levels in the blood, which leads to damage of the blood vessels.[7]

Diabetic foot ulcer (DFU) is one of the most feared complications of DM, leading to amputation and disability, social exclusion and early mortality. The lifetime incidence of foot ulcers has been estimated to be as high as 34 % of subjects with diabetes, while diabetes-related lower extremity complications affect an estimated 159 million people worldwide. Consequently, the diabetic population still contributes to 80 % of all non-traumatic lower extremity amputations worldwide.[11]

According to WHO, UPD is defined as infection, ulceration and destruction of deep tissues of the lower extremity, associated with neurological impairment and varying degrees of peripheral vascular disease. Age, poor metabolic control, abnormal immune response, deformities and the presence of vasculopathy and neuropathy are some of the risk factors closely related to its occurrence.[12]

UPD is an entity with an incidence of 2 % per year, which occurs, according to European studies, in 19 to 34 % of patients with diabetes mellitus during their lifetime. In Latin America, it is the reason for hospitalization in 3,7 % of cases and in 20 % of those hospitalized with diabetes mellitus.[13]

According to age, gender and place of origin, the prevalence figures of diabetic foot oscillate between 2,4 and 5,6 %. The incidence of foot ulcerations in these patients can reach 15 % of patients with diabetic foot. Up to 85 % of those who suffer amputations secondary to diabetic foot have previously suffered the appearance of a diabetic ulcer. In Argentina, 8 % of hospital beds are occupied by diabetic patients, generally with foot ulcers. Nineteen amputations are performed daily, approximately 7 000 per year, and 7 out of 10 are diabetic patients.[14]

It is estimated that 15 % of patients with diabetes will develop ulcers at some point in their lives. The treatment of diabetic foot is very expensive and takes a long time to heal. In Cuba, the Center for Genetic Engineering and Biotechnology (CIGB), an institution of the scientific pole of the capital, has developed the recombinant human epidermal growth factor through the drug Heberprot-P®, a unique product in the world, which has produced changes in the surgical concepts related to diabetic foot ulcers and has opened a range of therapeutic possibilities for these patients, with the improvement of their quality of life that is injected inside the lesion. This drug shows pharmacologically relevant properties, because it allows the establishment and consolidation of a useful and productive granulation tissue in diabetic patients with difficulty in healing. This includes de novo angiogenesis at the wound site; in addition, it stimulates the secretory phase in granulation particularly in patients with neuropathies, in whom granulation tissue is usually facellable, and wound contraction and remodeling.[15]

The treatment with Heberprot-P® in Cuba has marked a before and after, with very good results, included in a program of national and international scope for its implementation as an effective therapy to solve this problem in a high percentage of patients affected by UPD.[16]

Heberprot-P® has achieved the acceleration of ulcer healing, reducing the risk of amputation by 71 % in the Cuban population; it has been administered to more than 88 thousand patients in 12 years; and has prevented about 17 thousand amputations. Since 2007, when its application began in grade 3-4 ulcers, according to Wagner's International Classification, and in amputee patients, excellent results have been obtained, which have reduced the amputation rate and the average hospital stay. Likewise, it is currently used in all polyclinics in Cuba and in 37 countries of the world.[15]

The Cuban health system outlines strategies aimed at reducing disability in diabetic patients, thus contributing to a better quality of life of patients and their greater contribution to society, so it is feasible to conduct studies to evaluate the effectiveness of the different treatments applied and programs established to contribute to their improvement.

The objective of the article is to identify the factors that affect the response of diabetic foot ulcers to Heberprot-P® in patients of the polyclinic 5 de Septiembre, municipality Consolación del Sur of Pinar del Río province, during the period from January 2022 to January 2024.

METHOD

An observational, analytical, and cross-sectional study was carried out.

Universe: the universe was represented by all diabetic patients (n=1875) belonging to the "5 de Septiembre" health area of the Consolación del Sur municipality.

Sample: it was represented by all the patients with diabetic foot ulcer, treated with Heberprot-P® of the polyclinic 5 de Septiembre of the municipality Consolación del Sur, (n=28).

Inclusion criteria:

- Patients with the described characteristics who agreed to participate in the study.

Exclusion criteria:

- Patients for whom the final outcome of the treatment was unknown.
- In order to carry out the study, a survey was applied to collect the information that responded to the objectives of the research, with the prior informed consent of the participants.
- The information obtained from the registry of the municipal diabetic foot consultation was stored in a spreadsheet for its analysis, inferential statistics were used and different statistical tests were applied: absolute and relative frequency; Mann Whitney U test (p); Pearson's correlation.

RESULTS

Table 1 shows that in the sample there is a predominance of patients over 70 years of age with 64,2 % and female sex with 65,3 %.

Table1. Patients with diabetic foot ulcer treated with Heberprot-P® according to age and sex

Age (years)	Sex					
	Female		Male		Total	
	No.	%	No.	%	No.	%
Less than 60	6	21,4	0	0,0	6	21,4
60 to 69	3	10,7	1	3,6	4	14,3
From 70 to 79	4	14,3	5	17,9	9	32,1

Greater than 80	5	17,9	4	14,3	9	32,1
Total	18	64,3	10	35,7	28	100,0

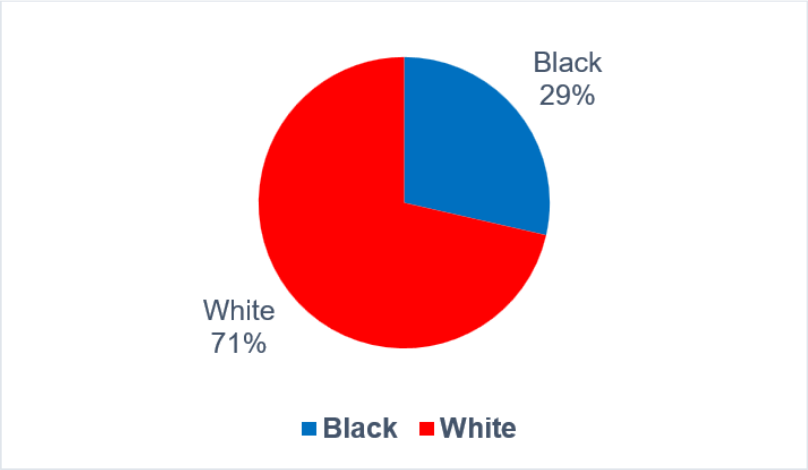

Figure 1. Patients with diabetic foot ulcer, treated with Heberprot-P® according to skin color

Figure 1 shows that the predominant skin color is white, representing 71 % of the total number of patients.

Table 2. Personal pathological history in patients with diabetic foot ulcer treated with Heberprot-P®

Variables	Yes		No	
	No.	%	No.	%
Arterial hypertension	15	53,6	13	46,4
Obesity	8	28,6	20	71,4
Ischemic heart disease	5	17,9	23	82,1
COPD	3	10,7	25	89,3

Table 2 shows that among the personal pathological antecedents of the group of diabetic patients studied, arterial hypertension is present in 56,3 % of the sample followed by obesity with 28,6 % of the patients investigated.

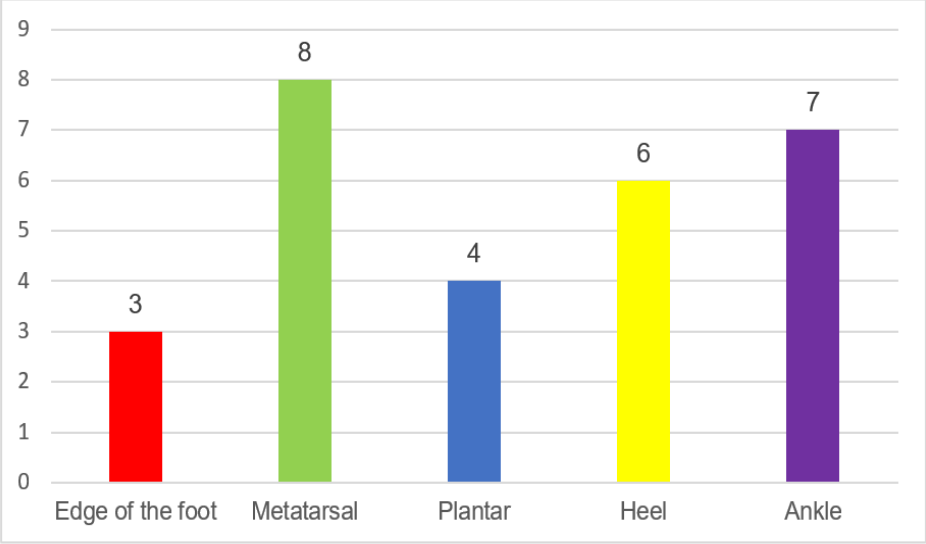

Figure 2. Anatomical location of diabetic foot ulcers

Figure 2 shows that the most frequent location in which ulcers are found in the group of people studied is the metatarsal region with 8 patients.

Table 3. Distribution of the sample according to time of healing of the lesion

Healing time (months)	No.	%	Mean	Minimum	Maximum
From 1 to 2 months and 30 days	17	60,7	2,64	1,0	6,0
3 to 4 months and 30 days	7	25,0			
5 to 6 months and 30 days	4	14,3			

Table 3 shows that 100 % of the patients studied had a diabetic foot healing, most of them, 60,7 % before 3 months, with a minimum of one month and a maximum of 6 months.

Table 4. Comparison of healing time taking into account the pathologic antecedents and toxic and dietary habits

Variables	Healing Time (months)		Mann Whitney U test (p)
	Yes	No	
	Mean	Mean	
Arterial hypertension	2,5	2,8	0,77
Obesity	2,8	1,5	0,01*
Smoking	3,2	1,8	0,04*
Ischemic heart disease	2,9	2,6	0,98
COPD	1,7	2,8	0,64
Feeding	Inadequate	Adequate	0,04*
	3,1	1,9	

Table 4 shows that when applying the Mann Whitney U test it was observed that in patients with obesity, smoking and an inadequate diet, the healing time of the lesion was significantly longer than in those who did not have these antecedents with 95 % certainty.

Table 5. Association between age and healing time

Variables	Pearson correlation	
	Correlation coefficient	p
Age (years)	0,52	0,00*

Table 5 shows that there is a statistically significant association between the age of the patient and the healing time with a p<0,05, this relationship is direct because as the age of the patient increases so does the healing time.

DISCUSSION

Diabetes mellitus is one of the greatest challenges in the field of chronic diseases, with an explosive increase of type 2, due to the growth and aging of the population, the increase in obesity, erroneous eating habits and sedentary lifestyle.[17]

The predominance of patients older than 70 years and female sex can be attributed to the higher frequency of diabetes mellitus after the sixth decade of life and in females, according to Cuban statistics.[9] In addition, this complication of diabetes tends to appear in patients with long evolution of the disease and even more with previous vascular alterations.

Age is recognized by different literatures as an important risk factor for chronic non-communicable diseases such as AHT and DM.[18]

Other authors such as Medina and Carbajales,[19] agreed with the predominance of patients in the 65-74 age group and female sex. As did Camaño and collaborators,[15] with a greater number of females and of the 60- and 69-years age group. Other studies published similar results.[17,20,21]

The greater number of patients with white skin color corresponds to the characteristics of the Cuban population, where this skin color predominates. Camacho and collaborators also had a predominance of patients with white skin color.[22]

The predominance of hypertensive and obese patients corresponds to the incidence of these diseases worldwide and in Cuba. Worldwide, more than one in five adults suffers from high blood pressure. The prevalence of hypertension worldwide in 2019 was highest in Central and Eastern Europe, Central Asia, Oceania, Southern Africa and some countries in Latin America and the Caribbean.[23]

Research addresses the high frequency of diabetic patients with hypertension and/or obesity.[24] Seguí and collaborators point out that there is a significant association between obesity, sedentary lifestyle and dietary

transgressions as risk factors for diabetes mellitus.[25] Mata also points out these risk factors as important predisposing factors for developing the disease, especially from the fifth decade of life onwards.[26]

The presence of lesions with predominance in the indicated sites, could be due to the use of inappropriate footwear for these patients, because they are areas exposed to friction with the footwear. Studies on the subject refer that the constant use of footwear with proven relief of the plantar pressure prevents the appearance and/or recurrence of plantar ulcers, specifically recurrent ulcers on the plantar surface of the metatarsal heads.[27]

Different studies have published favorable evolution with up to one hundred percent healing of the lesion with the use of Heberprot-P®.[16,28] López and collaborators,[20] also highlight the effectiveness of Heberprot-P® in achieving high healing and avoiding amputations.

The results presented in relation to healing time, taking into account the pathological antecedents, toxic and dietary habits, can be related to the effects of obesity, smoking and inadequate nutrition, the latter closely related to metabolic dyscontrol, on the blood vessels and the immune system which hinder the adequate irrigation of the tissue and its healing.

Martinez,[29] also reported an association between overweight or obesity and diabetic foot. Similar results were published by Gonzalez Lozada[30] Agurto Cruz,[31] concluded that overweight or obesity increases the risk complications of patients with neuropathy and diabetic foot by 52 %, these being the most complex, demonstrating the ineffectiveness of pharmacological treatments. As evidenced in the study.

CONCLUSIONS

In the sample studied there was a predominance of patients over 70 years of age, female sex and white skin color. Arterial hypertension and obesity are the most observed pathologic antecedents. The most frequent location of the ulcers was the metatarsal region followed by the ankle region, most of these lesions healed before 3 months. The healing time of the lesion shows a statistical relationship with the presence of obesity, smoking and inadequate nutrition, it is also observed that as the age of the patient increases, the healing time of the lesion also increases.

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CONFLICT OF INTEREST

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