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Artículos de Investigación

Compliance to treatment in diabetic patients from Bucaramanga, Colombia: a cross sectional study

Adherencia al tratamiento en pacientes diabéticos de Bucaramanga, Colombia: estudio de corte transversal

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Abstract: **Objective:** this study is aimed to evaluate knowledge about the disease, some behavioral habits and the level of compliance to pharmacological treatment, in a sample of diabetic patients, attending at hospital institution in the city of Bucaramanga (Colombia), during 2016. Diabetes mellitus is a chronic disease whose prevalence is increasing significantly in developing countries. **Materials and Methods:** cross sectional, descriptive study; a sample of 411 diabetic, aged over 35 years, who consulted at cardiovascular risk program, answered in the period between January and December 2016, a self-administered questionnaire that included the instruments IMEVID, Berbés and modified SMMS; Additionally, sociodemographic variables such as age, sex, stratum, education, were included. Results: 90% had a low socioeconomic status and 82.7% only reached primary studies or less. High Pharmacological adherence was observed in only 3.65%, medium adherence in 87.83% and low at 8.52%. Mean level of knowledge about diabetes was 13.32; Almost half (46.72%) scored below the average; Mean of glycosylated hemoglobin was 7.93%; 34.8% scored above this value. 18.7% have an inadequate lifestyle (IMEVID score <60). Low adherence found associated with: alcohol intake, IMEVID score <60, Ask more after eating, have a job and don't use insulin. **Conclusion:** it is necessary to establish learning strategies and methodologies of motivation and training for diabetic patients, to improve quality of life and knowledge of the diabetes and, in this way, optimize the prognosis of the disease.

Keywords: diabetes mellitus, patient compliance, healthy lifestyle, patient medication knowledge.

Resumen: Objetivo: el estudio se propone evaluar el conocimiento sobre la enfermedad, algunos hábitos de comportamiento y el nivel de cumplimiento con el tratamiento farmacológico en una muestra de pacientes diabéticos que asistieron a una institución hospitalaria en la ciudad de Bucaramanga (Colombia) durante el 2016. La diabetes mellitus es una enfermedad crónica, su prevalencia está aumentando significativamente en los países en desarrollo. **Materiales y Métodos:** estudio de corte transversal, descriptivo; una muestra de 411 diabéticos, mayores de 35 años, que consultaron al programa de riesgo cardiovascular, respondieron en el período comprendido entre enero a diciembre de 2016, un cuestionario autoadministrado que incluía los instrumentos IMEVID, Berbés y SMMS modificado; Adicionalmente, se incluyeron variables sociodemográficas como edad, sexo, estrato, educación. **Resultados:** el 90% tenía un estatus socioeconómico bajo y el 82.7% solo alcanzó estudios primarios o menos. Se observó una alta adherencia farmacológica en solo el 3,65%, una adherencia media en el 87,83% y una baja en el 8,52%. El nivel medio de conocimiento sobre la diabetes fue de 13.32; Casi la mitad (46.72%) puntuó por debajo del promedio; La media de hemoglobina glicosilada fue de 7.93%; El 34.8% puntuó por encima de este valor. El 18.7% tiene un estilo de vida inadecuado (puntuación IMEVID <60). Se encontró que la baja adherencia estaba asociada con: consumo de alcohol, puntaje IMEVID <60, pedir más después de comer, tener un trabajo y no usar insulina. **Conclusión:** es necesario establecer estrategias de aprendizaje y metodologías de motivación y entrenamiento a los pacientes diabéticos, para mejorar la calidad de vida y el conocimiento de la diabetes, y de esta manera, optimizar el pronóstico de la enfermedad.

Palabras clave: diabetes mellitus, cooperación del paciente, estilo de vida saludable, conocimiento de la medicación.

Introduction

Diabetes mellitus (DM) is a chronic disease whose pathophysiological substrate is characterized by the inability of the pancreas to synthesize or release insulin or, when the cells gradually lose the ability to incorporate and use insulin. Currently, DM has been recognized as a public health problem worldwide [1]. In 2015, it is estimated that, in the world, around 415 million suffer of this disease and 318 million have prediabetes, that is, they are at risk of developing microvascular complications, since global prevalence has almost doubled in the period 2014 - 2018 [2]. In high-income countries, DM implies very high costs of care, due to the occurrence of major cardiovascular diseases such as blindness, kidney failure and lower limb amputation, sequelae consistent with deficient control of DM. Maintaining blood levels of blood glucose, blood pressure and cholesterol close to normal can help delay or prevent the progression of DM [3].

In the perspective of the care and clinical control of the diabetic patient, efforts are focused on balancing serum glucose levels, for which drug-therapeutic interventions and changes in lifestyle habits are designed, especially in the diet, physical activity and self-care by the patient. The biggest obstacle in this perspective is given by the urgent need for the patient to accept and adopt a lifestyle, frequently extent unusual, because the magnitude of the restrictions that must be adopted to achieve stability [3]. This is reflected because around 50% of patients maintain blood sugar levels above the recommended limits [4].

With the aim of establishing the magnitude of events in which the patient follows the self-care instructions and complies with the

indications of therapeutic prescription, various terms have been coined from the academy to identify this dimension. Thus, the terms adherence, attachment, compliance (in English, the most used are compliance and adherence) [5]. There are multiple definitions that aim to integrate this concept, adherence is defined as the event in which two conditions are positive: compliance in the taking of medications and persistence during the formulation time [6].

Another definition disseminated by the World Health Organization (WHO), considers adherence as “a continuum in which, each patient reaches a degree of self-behavior focused on the taking of medicines, monitoring a diet and acquisition of habits that configure a healthy lifestyle, in correspondence with the recommendations given by a health agent”, in this case, the definition goes beyond the concept of pharmacological adherence, because it also involves behavioral changes [7].

What really is considered an aspect of singular importance, in the case of the DM, is to be able to access indicators of adherence, through procedures that can be direct or indirect. In our environment, indirect methods are more common, given the ease of application of previously designed and validated questionnaires or questionnaires [8], of which in the case of DM, the most used is that of Morinsky-Green, which consists of four questions that inquire about whether the patient takes the medication, if he forgets to take it and if he suspends it when he feels good or bad, although this scale only quantifies the behaviors related with the fact of taking the medication [9].

Another important factor to consider, in order to study in depth the phenomenon of adherence, is related to the costs and the quality and duration of life in patients affected by DM, since the adequate control of the glycemia levels, depend principally of the cardiovascular integrity and, of certain particularly labile structures such as feet, peripheral nerves, eyes and kidneys [10]. The aim of this study was to evaluate the knowledge about the disease, behavioral habits and the level of compliance to pharmacological treatment, in diabetic patients attending a hospital institution in the city of Bucaramanga, during 2016.

Materials and methods

There was designed an observational, descriptive, cross sectional study. The target population was the community of patients diagnosed as DM, who attend to the cardiovascular prevention program at the Local Hospital of the North (HLN) located at the city of Bucaramanga (Colombia). The study was approved by the Institutional Ethics Committee of the HLN. All potential participants were duly informed of the study object and methodology and them expressed their consent to participate, in each moment, the researchers procured to respect confidentiality and privacy of the subjects.

Sample size was estimated from a reported prevalence of adherence to treatment of 34.1% [11], with type I error of 0.05, an acceptable

margin of error of 5% and type II error of 20%, which yielded a sample size of 398 patients, selected from a target population of about 1200 diabetics enrolled in the cardiovascular risk program; finally, 411 people who met the eligibility criteria were linked; they answered a self-administered questionnaire in the period between January to December 2016. Sampling was carried out following a non-probabilistic sequential plan, as a result of which a total of 411 patients were interviewed. The inclusion criteria were taken into account: men and women over 35 years of age, with a confirmed diagnosis of DM, linked to the cardiovascular risk program of the Hospital del Norte de Bucaramanga. As exclusion criteria, the habitual consumption of steroids by any medical indication, pregnant women, terminal illness, severe prostration, iron deficiency anemia or manifest inability to answer the questionnaire was considered.

Sources of information were a survey that included sociodemographic variables (sex, age, occupation, socioeconomic stratum and type of affiliation to the Health System), clinical variables (time elapsed since the diagnosis of DM, glycemia values and glycosylated hemoglobin at the time of the last control). For the purposes of quantifying the degree of pharmacological adherence, lifestyle and knowledge about the disease, the following instruments were included: the modified 4-item Morinsky-Green questionnaire, the IMEVID questionnaire and the Berbés questionnaire.

The modified Morinsky-Green questionnaire is an instrument conformed of 4 questions, which ask about whether the patient takes the medication, if he forgets to take it and if he usually suspends it when he feels good or bad; This is a context, in addition to the therapeutic regimen, such as diet, physical activity and control of associated risk factors [12]. the Spanish version of this scale was validated by Val-Jiménez et al. [13].

The IMEVID questionnaire. The IMEVID (Instrument to Measure the lifestyle in Diabetics), helps the primary care physician to quantify the lifestyle of patients suffering DM, considering the following dimensions: nutrition, physical activity, tobacco consumption, alcohol intake, knowledge about diabetes, emotion management and therapeutic compliance. This questionnaire consists of 25 closed questions. Each item presents three response options with ratings of 0, 2 and 4, where 4 corresponds to the maximum desirable value in each response, for a total score of 0 to 100, with no odd values on the scale. moreover, this result allows patients to be classified into 3 groups: the first: ≤ 60 , group 2: 60-78 and group 3, ≥ 80 . allowing in this way, an adequate analysis of patients according to their score; the Spanish version of this scale was validated by López-Carmona et al. [14].

The Berbés questionnaire, is an instrument that allows assessing the degree of knowledge of the patients about their disease, expressed in the case of evaluation studies as mean \pm standard deviation (SD). The instrument consists of 18 questions: 13 scored from -1 to 1 and 5 questions scored from -2 to 2; with which the score of the test can range between -23 and 23 points [13]; the Spanish version of this scale was validated by Andrés-Iglesias et al. [15]. Data were collected in the

period between February and December 2016, through structured direct interview.

Statistical analysis. It was used the Epi-Info^{7™} program (OMS-CDC Atlanta, USA). Qualitative data are expressed as percentages and the quantitative data as mean and standard deviation according with the frequency distribution. Confidence limits were calculated at 95% (CI), using the Chi² tests for qualitative variables and, in the case of small samples, the Fisher variant. Student's t test for quantitative variables when the distributions were normal (Kolmogorov test with the Lilliefors corrections) and Mann-Whitney (Wilcoxon) for variables without normal distribution. The correlations were determined by the Pearson r or Spearman's Rho according to whether or not they were parametric variables. The statistical significance was fixed at $p < 0.05$. Bias control was achieved by sample size and diagnostic verification. The included confounding variables were the subject of stratified analysis.

Results

Characterizing the sample. Of 411 subjects, 76.6% ($n = 315$) were female; mean age was 62.25 years ($SD = 11.7$, range 35-93), no statistically significant differences were found in the mean age by sex ($p = 0.17$); 67.7% of male with stable partners, in contrast to 43.5% female ($p = 0.0001$). Only 1.95% of the subjects are jubilated, while 79.8% are unemployed. 90% belong to socioeconomic stratum 1-2, only 9.9% stratum 3-4. 82.7% barely reached complete primary education or less. 96.3% are linked to the health system in the subsidized modality, while only 3.7% are as contributory.

The average value of fasting blood glucose was 162.42 mg / dL ($SD = 78.02$) with a statistically significant difference in benefit of female (159.27 ± 71.9 mg / dL) compared to men (172.75 ± 94.9 mg / dL).

The mean value of the glycosylated hemoglobin was 7.93% ($SD = 2.13$, range 5-16.5%); no statistically significant differences were found by sex. 59.65% ($n = 241$) of the patients registered fasting blood glucose above 126.0 mg / dL, which reflects inadequate management and control of diabetes. 34.8% ($N = 143$) registered percentages above 8%, which is interpreted as inadequate control of serum levels of glycemia, during at least the last three months.

There was a low degree of positive correlation between the values of fasting glycemia and the glycosylated hemoglobin, the Pearson correlation coefficient (R) was 0.58; the goodness of fit, expressed as $R^2 = 0.34$; p value ($\text{Prob} > F$) = 0,0000 (Figure 1).

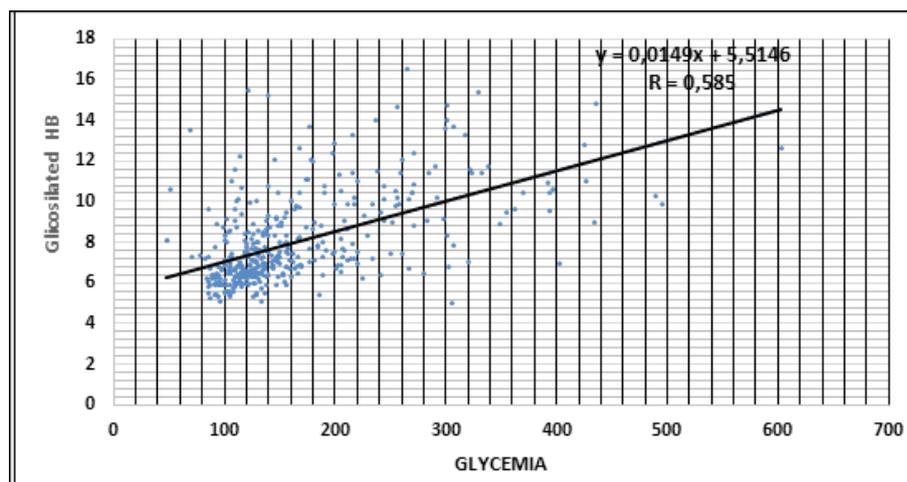


Figure 1
 Correlation between Glycemia and Hemoglobin Glycosylated (HbA1C).
 Diabetic patients from Bucaramanga 2016. (Prob. > F= 0,0000).
 Database. Own elaboration

The mean time of permanence as diabetic patient was 6.95 years (SD = 6.46, range 0.1-45); no statistically significant differences were found by sex. 34.8% of patients (n = 140) are located above this average. Table 1 shows the frequency with which these patients attend to control meet.

Frequency	Number	%
Monthly	176	42.93%
Bimonthly	49	11.95%
Quarterly	158	38.54%
Biannual	18	4.39%
Annual	9	2.20%
Total	410	100.00%

Table 1
 Frequency of the control meet. Diabetic patients from Bucaramanga, 2016.
 database. Own elaboration.

36.74% (n = 151) are insulin-dependent while the others consume other types of medications, mainly oral hypoglycemia agents. The most used insulin is the prolonged release one.

In measuring the lifestyle of diabetics, the starting suppose, is that when higher scores are in the IMEVID instrument, the levels of fasting blood glucose and glycosylated hemoglobin must be lower. The mean score of the IMEVID test was 69.73 (SD = 9.62, range 40-94); Table 2 shows the mean values of glycosylated hemoglobin and glycemia in relation to the score group reached in the IMEVID questionnaire. There were no statistically significant differences between the groups (p> 0.05).

IMEVID SCORE	Frequency (%)	Mean HbA1C (SD)	Fasting blood glucose (SD)
60 or LESS	77 (18.7)	7.64 (1.91)	163.55 (84.8)
61 - 79	267 (64.9)	8.04 (2.14)	165.68 (79.2)
80 or MORE	67 (16.3)	7.86 (2.31)	148.12 (63.4)

Table 2

Mean values of Glycosylated Hemoglobin (HbA1C) and fasting blood glucose accord to IMEVID score. Diabetic patients from Bucaramanga, 2016. database. Own elaboration.

In the assessment of the degree of knowledge that patients have about the disease, the mean score was 13.32 (SD = 4.5, range 4 - 23). Almost half, that is, 46.72% (n = 192) of the subjects scored below the mean; Table 3 correlates the scores obtained in the IMEVID and Berbés tests by the patients included.

IMEVID SCORE	BERBES SCORE		Total
	LESS THAN MEAN	ABOVE MEAN	
60 OR LESS	40	37	77
%	51,95%	48,05%	
61 - 79	123	144	267
%	46,07%	53,93%	
80 OR MORE	29	38	67
%	43,28%	56,72%	
TOTAL	192	219	411

Table 3

Relationship between the scores in the test IMEVID and Berbés. Diabetic patients from Bucaramanga, 2016.

database. Own elaboration

Using the modified Morinsky-Green questionnaire, the degree of pharmacological adherence to the treatment of diabetes was estimated; it was found to be high in only 3.65% (n = 15) patients, medium in 87.83% (n = 361) and very low in 8.52% (n = 35).

In an exploratory way, there were sought to establish some degree of causal association between the low level of pharmacological adherence with some factors present in the corresponding instruments. Table 4 shows the most significant correlations that were found.

VARIABLE	EXPOSURE	ADHERENCE		OR	IC95%	p
		LOW	MEDIUM/HIGH			
ALCOHOL INTAKE	YES	13	40	4,94	2,13-10,5	0,0001
	NO	22	335			
IMEVID <60	YES	16	61	4,34	2,11-8,92	0,00001
	NO	19	315			
ASK FOR MORE AFTER EATING	YES	7	39	2,39	0,98-5,83	0,0367
	NO	28	373			
glyco sylate d Hemoglobin <8,0	YES	28	240	2,26	0,96-5,32	0,05
	NO	7	136			
HAVE A JOB	YES	23	305	2,24	1,06-4,71	0,0304
	NO	12	71			
DONT USE INSULIN	YES	27	231	2,40	1,02-5,66	0,0271
	NO	7	144			

Table 4

Assessing possible association between low pharmacological adherence to treatment and some possible risk factors. Diabetic patients from Bucaramanga 2016.

database. Own elaboration

Discussion

There is a worldwide consensus that the management of diabetic patients can't be restricted to drug-therapy; The integral and rational management of the DM disease requires the adoption of a lifestyle that includes: an strict and balanced diet, regulated and constant physical activity, permanent control of body weight and abandonment of potentially harmful habits such as smoking and exaggerated consumption of alcoholic beverages [16].

Although the majority of patients registered a medium level of adherence to pharmacological treatment, it's worrisome that this indicator is not optimal for most patients; It is convenient to review in detail the strategy and methodology of training and motivation, that should be included for the diabetic patient control program, which in essence should include the social and sociocultural aspects that have the most significance for the purpose of achieving a more committed attitude to self-care and rigor in aspects such as diet, physical activity and hygienic precautions [17].

There is some consensus, considering that the complications of diabetes can be significantly reduced if patients persist on maintaining adequate control of their glycemic figures, by combining therapeutic measures and self-care, particularly because intensive control of blood glucose by reducing the overall rate of microvascular complications by up to 25% [18].

It is also important to consider that a significant majority of the population included in the study has a very low grade of education, too a precarious socioeconomic status, then, they come from a segment of the population living in poverty, which is why it is very important the design and implementation of educational and training strategies that guarantee a high impact on the socio-cultural and economic aspects mentioned, which should undoubtedly be expressed in the significant changes in the style of life, quantifiable in the IMEVID instrument and also on the level

of knowledge about diabetes, measurable through the Berbés instrument [19].

Several studies have shown that the level of knowledge about the disease significantly affects the quality of life and the degree of compliance of patients, since dissatisfaction results in demotivation and skepticism about achieving an appropriate level of well-being [20].

The glycosylated hemoglobin is emerging as a very reliable indicator of the degree of control, acceptance and adherence of the patient to pharmacological treatment and to the patterns of behavior and diet that turn out to be significantly beneficial for the management and control of their disease, since it allows to a certain extent predict microvascular lesions as well as the circulatory system in general. When comparing the levels of glycosylated hemoglobin with lifestyle, the level of knowledge about the disease, the time of evolution and the degree of acceptance and adherence, it is found that when the lifestyle is appropriate and patients have adequate knowledge of the disease is more likely to achieve metabolic and functional stability, expressed as glycosylated hemoglobin values less than 8% [19].

The low degree of economic status that was found in this study shows forward another disadvantage, constituted by the degree of food security of adults with diabetes, a concept that implies having access to a healthy diet. It has been seen that, in populations with high index of food insecurity, consumption of sugars and carbohydrates soars, while in communities that enjoy food security there is a better dietary balance [21].

Limitations of this study

Although this study offers a panoramic view of the problem that occurs with the adherence and knowledge of diabetic patients about their disease, it is important to consider that because it is a cross-sectional study, the results should be taken with caution, since it offers a perspective, but not It can be considered a conclusive result. In any case, these results invite to carry out analytical studies designed with greater rigor approach.

Conclusions

It is found in the group of diabetics treated in the Hospital del Norte de Bucaramanga, a very low socioeconomic and educational level that, coupled with pedagogic and strategic deficiencies in health education and lack of motivation aimed at adopting an appropriate lifestyle. the disease, lead to a very low percentage of high adherence to pharmacological treatment.

Conflict of interest: none

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