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Original Article

Adherence to the treatment with oral antidiabetic medications in primary health care

Adesão ao tratamento com antidiabéticos orais na atenção básica de saúde

Adherencia al tratamiento con antidiabéticos orales en atención primaria de salud

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Objective: to assess the level of adherence to the drug treatment with oral antidiabetic medications in the primary health care network. **Methods:** analytical, quantitative study conducted with 63 patients with diabetes mellitus type 2 attended in three Basic Health Units. One used a form which included sociodemographic and clinical information related to treatment adherence, assessed through the Morisky-Green test. **Results:** it was found that 22.2% of the patients adhered to the treatment. There were no statistically significant correlations between adherence and sociodemographic and clinical variables. **Conclusion:** non-adherence was high, requiring intervention measures to correct the problem and to promote a better quality of life for patients with diabetes mellitus type 2.
Descriptors: Diabetes Mellitus Type 2; Patient Compliance; Nursing.

Objetivo: avaliar o nível da adesão ao tratamento medicamentoso com antidiabéticos orais na rede de atenção básica. **Métodos:** estudo analítico, quantitativo, realizado com 63 pacientes com diabetes mellitus tipo 2 acompanhados em três Unidades Básicas de Saúde. Utilizou-se formulário que contemplou informações sociodemográficas e clínicas, e relacionadas à adesão ao tratamento, avaliada por meio do teste indireto de Morisky-Green-Levine. **Resultados:** verificou-se que 22,2% dos pacientes aderiam ao tratamento. Não houve correlações estatisticamente significantes entre adesão e as variáveis sociodemográficos e clínicas. **Conclusão:** a não adesão foi elevada, necessitando de medidas de intervenção para corrigir tal problema e promover melhor qualidade de vida aos pacientes com diabetes mellitus tipo 2.
Descritores: Diabetes Mellitus Tipo 2; Cooperação do Paciente; Enfermagem.

Objetivo: evaluar el nivel de adherencia al tratamiento farmacológico con fármacos antidiabéticos orales en la red de atención primaria. **Métodos**: estudio analítico, cuantitativo con 63 pacientes con diabetes mellitus tipo 2 acompañados en tres Unidades Básicas de Salud. Se utilizó el formulario con las informaciones sociodemográficas y clínicas relacionadas con la adherencia al tratamiento, evaluada a través de la prueba indirecta de Morisky-Green-Levine. **Resultados**: 22,2% de los pacientes se adhirieron al tratamiento. No hubo correlaciones estadísticamente significativas entre adherencia y las variables sociodemográficas y clínicas. **Conclusión**: la falta de adherencia fue alta, lo que requiere intervención para corregir el problema y promover mejor calidad de vida a pacientes con diabetes mellitus tipo 2.
Descriptores: Diabetes mellitus tipo 2; Cooperación del Paciente; Enfermería.

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Introduction

Diabetes Mellitus is considered a significant public health problem because of its prevalence and incidence in epidemic proportions. It has been estimated that there are 371 million diabetic people in the world. Brazil is in fourth place among the countries with the highest prevalence of diabetes mellitus and recent projections indicate that there are 13.4 million diabetic people in this country, which is equivalent to 6.5% of the population between 20 and 79 years old[1].

The maintenance of glycemic and metabolic control in people with diabetes mellitus is directly related to the treatment, whether with or without medications. Despite the development of drugs and care strategies for this group, the control of this disease and the reduction of morbidity and mortality has not reached the desired levels and one reason for this problem has been the non-adherence to the treatment[2].

It is known that the non-adherence to the treatment may bring serious repercussions for patients with diabetes mellitus. Studies confirm that a low adherence to the treatment regimens may be the primary reason to the reduction of clinical benefits, which leads to health complications, psychosocial complications and it reduces the population's quality of life[3-4].

Statements like these make the scientific community to sensitize and to conduct research to identify non-compliant patients, so that, through a situational diagnosis, intervention measures can be drawn and directed to the people involved.

Different health professionals have conducted cross-sectional studies in order to assess medication adherence of patients with diabetes. One of these professionals who is worth mentioning is the nurse, as pointed out by an investigation conducted with 437 diabetic patients, treated at the primary health care network of Fortaleza, Ceará and which aimed to assess adherence to oral antidiabetic medications[5]. Another study, also conducted by nurses, emphasizes the need for the reorganization of health care services to the people with diabetes mellitus, which should ensure, besides the supply of medicinal products, their proper use to obtain the desired therapeutic effect[6].

The reason for emphasis lies in the fact that this professional category is the one that spends more time next to patients, either in basic health care services in Brazil, through the reorientation model of assistance of the Family Health Strategy, or in the other levels of complexity, acting directly in clinical care. For this reason, in most cases, nurses are the ones who detect non-adherence to the treatment, whether with or without medication. But these professionals need the problem of non-compliance to be identified and measured more thoroughly, such as with the application of indirect tests. Through the data obtained, nursing starts to have subsidies to diagnose nursing problems, to plan, implement and evaluate specific actions of intervention, whose main objective is the promotion of patients' health and the consequent improvement in their quality of life.

Searches conducted in the literature have shown that studies about the issue of medication adherence, especially with oral antidiabetic medications in the state of Piauí, Brazil are still not enough. The lack of data may jeopardize the planning and implementation of actions to improve the metabolic control and decrease the occurrence of chronic complications of diabetic patients. It is from the knowledge gap observed, from the relevance of this topic and from the need to trace intervention measures that this study was conducted with the main objective of assessing the level of adherence to the drug treatment with oral antidiabetic medications in the primary health care network in Floriano-PI-Brazil.

Method

This is an analytical, quantitative study conducted with diabetic patients of both sexes, registered and attended in basic health units intended

for treatment of patients with diabetes mellitus type 2, in the city of Floriano-PI, Brazil.

It is worth highlighting that this study stems from a larger project, still in progress, which aims to assess medication adherence in all basic health units from Floriano-PI. Moreover, it was awarded the notice FAPEPI/SESAPI/MS/CNPq/No. 003/2013 from the research program for the Unified Health System: shared management in health - Edition 2012.

For the sample size calculation, one used the formula for finite populations, using therefore: 95% confidence interval, P=50%, Q=50% and sample error of 4%. After the appropriate calculations, the sample size resulted in 393 patients, distributed in the 17 basic health units of the municipality. Every basic health unit had their sample calculated by stratification.

However, for this study, 63 subjects composed the sample divided into three Basic Health Units of this municipality from Piauí.

One used as inclusion criteria: having been diagnosed with diabetes mellitus type 2; being attended in the services of the primary health care network from Floriano-PI; being treated with oral antidiabetic medications; having the same medical prescription for at least six months; have medical record or health record available at the service; having physical and mental conditions to answer the interview questions. The study excluded patients who used insulin and pregnant women.

Data collection was conducted from December 2013 to February 2014. It was used a form for collecting information which included sociodemographic data (age, sex, marital status and work situation, social class, among others.), anthropometric and clinical data (height, weight, nutritional status, blood pressure and physical inactivity) and indicators related to medication adherence (assessed by Morisky-Green-Levine test).

The anthropometric data (weight and height) were evaluated only once, using some care measures. Weight was obtained with patients barefoot and wearing light clothes, through the use of a digital portable scale with a capacity of 150 kg and a precision of 0.1 kg. Height was verified with a tape with a scale of 0.5 cm. In order to ensure measurement accuracy, respondents were asked to stay erect and motionless, hands flat on their thighs and heads adjusted to the Frankfurt plane. After weight and height measurements, the body mass index was calculated, defined as the ratio between weight (kg) and the square of height (m). One considered as overweight subjects with values between 25.0 and 29.9 kg/m^2; and obese those with body mass index ≥ 30 kg/m^2[7-8].

The measurement of arterial blood pressure as well as the preparation routine of individuals and the blood pressure value was based on the VI Brazilian Guidelines of Arterial Hypertension[9].

In order to explore the sedentary lifestyle, patients were evaluated from the perspective of self-reported information. Patients who reported doing physical activities for less than 30 minutes and less frequently than three times a week were classified as sedentary[10].

To classify patients as adherent or non-adherent to the treatment with oral antidiabetic agents, one considered[11] the Morisky-Green-Levine Test. This test, which has been used in other studies conducted by nurses[5-7], assesses the compliance through dichotomous questions (yes/no) regarding patients' attitudes about the use of medications. One highlights that this test has already been adapted to assess medication adherence levels in patients with different diseases, such as hypertension, heart failure and diabetes[7,12 -13].

Here are dichotomous questions that aim to evaluate patients' behavior regarding the frequent use of medication: 1) Have you ever forgotten to take the pills for diabetes? 2) Have you ever been careless with the time to take the pills for diabetes? 3) Have you ever stopped taking the pills for diabetes, because you felt better? 4) Have you ever stopped taking the pills for diabetes on your own initiative, due to feeling worse? 5) Have you over taken one or more pills for diabetes on your own initiative, due to feeling worse?

6) Have you ever stopped taking the pills for diabetes for running out of medication? One considered non-compliant with the medication therapy the participants who answered yes to at least one of the items presented.

Data were entered in an Excel® spreadsheet and analyzed using Epi Info software version 3.5.2. The statistical measures of quantitative variables were calculated: mean and standard deviation. Also, combination tests were carried out between the drug adhesion and the study variables. For all the inferential statistics analyses, one considered as statistically significant those with $p<0.05$. In order to verify the existence of associations between the study variables, crossed tables were made and the Fisher test was applied. It is aimed to determine the exact probability of an observed frequency and it is indicated when the size of the independent samples is small.

As for the ethical aspects, the study was approved by the Ethics Committee of the Federal University of Piauí *[Universidade Federal do Piauí]*, under opinion no. 485,420. Patients who agreed to participate signed a free and informed consent form, which contained detailed information about the study, the freedom to quit at any time, the guarantee of anonymity and also that the study would not bring any damages or complications to the participants.

Results

Considering participants' self-reported sex and color, it can be inferred that there was a bigger participation of women (76.2%), brown people (55.6%) and black people (23.8%). The age of the individuals surveyed ranged from 36 to 89 years old, mean of 62.2 years old (±SD 10.8). Another highlighted characteristic was the low educational level. Approximately 78.0% of the patients were illiterate and/or had not finished elementary school. Concerning social class, it became evident a low income scenario, since more than half of the subjects belonged to D and E social classes (55.6%).

The analysis of their nutritional status through the body mass index, revealed that 79.4% of the patients were overweight, being 41.3% overweight and 38.1% obese. It can also be observed that the sedentary lifestyle was present in large proportions (71.4%).

Table 1 - Distribution of sociodemographic and clinical characteristics of patients with DM2 using oral antidiabetic medications

Characteristics	n (%)
Sex	
Female	48 (76.2)
Male	15 (23.8)
Marital Status	
Married / Stable union	31 (49.2)
Single	9 (14.3)
Widowed	21 (33.3)
Separated	2 (3.2)
Education	
Did not study/ Functional Illiterate	13 (20.6)
Incomplete Elementary School	36 (57.1)
Complete Elementary School	10 (15.9)
Incomplete High School	1 (1.6)
Complete High School	3(4.8)
Employment Situation	
Formal job	3 (4.8)
Informal job	4 (6.3)
Unemployed	1 (1.6)
Retired	24 (38.1)
Housewife	31 (49.2)
Housing	
Own	60 (95.2)
Rented	3 (4.8)
Social Class	
B	2 (3.2)
C	26 (41.3)
D-E	35 (55.6)
Nutritional Status	
Eutrophic	13 (20.6)
Overweight	26 (41.3)
Obesity	24 (38.1)
Hypertension	
Yes	20 (31.7)
No	43 (68.3)
Physical inactivity	
Yes	45 (71.4)
No	18 (28.6)

Regarding the data about adherence to the treatment, specifically in the case of forgetting to take oral antidiabetic medications, 39 (61.9%) subjects responded negatively to this question. As to the time of taking the medication, 37 (58.7%) diabetic patients reported being careless. It is worth mentioning that smaller amounts of patients reported taking more than one or several oral antidiabetic drugs on their own initiative, after they felt worse and having already discontinued the treatment for diabetes, for running out of medication (Table 2)

Table 2 - Distribution of diabetic patients according to the questions of Morisk-Green-Levine Test

Questions	n (%)
Have you ever forgotten to take the pills for diabetes?	
Yes	24 (38.1)
No	39 (61.9)
Have you ever been careless with the time to take the pills for diabetes?	
Yes	37 (58.7)
No	26 (41.3)
Have you ever stopped taking the pills for diabetes because you felt better?	
Yes	10 (15.6)
No	53 (84.1)
Have you ever stopped taking the pills for diabetes on your own initiative because you felt worse?	
Yes	6 (9.5)
No	57 (90.5)
Have you taken more than one or several pills for diabetes on your own initiative, because you felt worse?	
Yes	3 (4.8)
No	60 (95.2)
Have you ever discontinued the treatment with the pills for diabetes for running out of medication?	
Yes	16 (24.4)
No	47 (75.6)

Finally, the result of medication adherence, revealed that 77.8% of the patients were considered non-adherent to the treatment with oral antidiabetic agents (Figure 1).

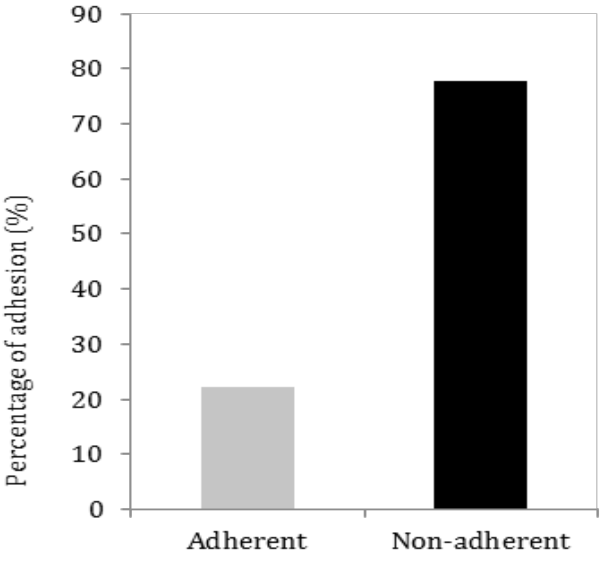

Figure 1 - Level of adhesion to the treatment with oral antidiabetic medications through Morisk-Green test

Regarding the intersection between the adhesion, and the socioeconomic variables, one noticed that the non-adherence to the medication was in higher proportions among male patients, who were married or had stable union, who had not studied or were functional illiterate, unemployed, with rented housing and who belonged to the B social class. However, in none of the intersections conducted one found statistically significant association (Table 3).

Table 3 - Association between the level of adherence to the drug treatment through Morisk-Green-Levine Test and the sociodemographic variables

Variables	Adhesion		p value
	Yes n(%)	No n(%)	
Sex			0.560*
Female	11 (22.9)	37 (77.1)	
Male	3 (20.0)	12 (80.0)	
Marital status			0.784*
Married/Stable union	6 (19.4)	25 (80.6)	
Single	2 (22.2)	7 (77.8)	
Widowed	5 (23.8)	16 (76.2)	
Separated	1 (50.0)	1 (50.0)	
Education			0.393*
Did not study/Functional Illiterate	2 (15.4)	11 (84.6)	
Incomplete elementary school	8 (22.2)	28 (77.8)	
Complete elementary school	2 (20.0)	8 (80.0)	
Incomplete high school	1 (100.0)	-	
Complete High School	1 (33.3)	2 (66.7)	
Employment Situation			0.968*
Formal job	1(33.3)	2 (66.7)	
Informal job	1(25.0)	3 (75.0)	
Unemployed	-	1 (100.0)	
Retired	5(20.8)	19 (79.2)	
Housewife	7(22.6)	24 (77.4)	
Housing			0.463*
Own	14 (23,3)	46 (76.7)	
Rented	-	3 (100.0)	
Social Class			0.334*
B	-	2 (100.0)	
C	8 (30.8)	18 (69.2)	
D-E	6 (17.1)	29 (82.9)	

*Fisher's exact test

In order to explore the relationship between medication adherence in diabetic patients, from Morisky-Gree-Levine test, it was also conducted the intersection of adherent and non-adherent patients with the clinical variables of the study. The results showed higher rates of non-adherence in diabetic patients with obesity (83.3%), hypertension (80.0%) and sedentary lifestyle (80.0%). However, for these variables, there was no statistically significant association (Table 4).

Table 4 - Association between the level of adherence to the drug treatment through the Morisk-Green-Levine Test and the clinical variables

Variables	Adhesion		p value
	Yes n(%)	No n(%)	
Nutritional State			0.681*
Eutrophic	3 (23.1)	10 (76.9)	
Overweight	7 (26.9)	19 (73.1)	
Obesity	4 (16.7)	20 (83.3)	
Hypertension			0.523*
Yes	4 (20.0)	16 (80.0)	
No	10 (23.3)	33 (76.7)	
Sedentary lifestyle			0.360*
Yes	9 (20.0)	36 (80.0)	
No	5 (27.8)	13 (72.8)	

*Fisher's exact test

Discussion

The sample of this study was characterized by the higher prevalence of females (76.2%) and average of 62.2 years old. Studies claim that the female population actually predominates over males among patients with diabetes mellitus[14]. The reason for the high number of female patients is the fact that men do not seek, as women do, primary health care services, entering the system through ambulatory and hospital care of medium and high complexity, whose consequences are: aggravation of morbidity by delay in care and a larger cost to the health system. The relationship between the average age and the prevalence of diabetes mellitus type 2 is according to the literature, as it highlights that the frequency of this disease increases gradually after 50 years of age[15-16].

Among the participants in this study, there was a predominance of participants who were married/had stable union (49.2%) and widowed (33.3%). This fact was already expected, since the population affected by diabetes mellitus type 2 tends to be over 45 years old, so it was expected that they would already be in a stable union or, at worst, in widowhood.

Regarding education, it was evident that the sample had low education. This fact interferes with

self-care, as it becomes an aggravating factor due to the impairment of reading, writing and understanding skills of educational activities. In this context, diabetic patients' understanding about their condition interferes with their control, prevention and even with the retardation of onset of acute and chronic complications, as well as with the maintenance of their quality of life[17].

Given the socioeconomic characteristics it is important to rethink the actions of health education carried out by professional staffs of basic health units, especially with regard to the guidelines for self-care, questioning about the social and cultural context in which patients live, thus improving the resources they have in order to develop healthier lifestyle habits.

In terms of nutritional status, one found significant percentage of overweight. It is important to emphasize that obesity is a predisposing factor for the development of diabetes mellitus type 2, as well as for hypertension and dyslipidemia. It is estimated that 80% of patients with diabetes mellitus type 2 present obesity or overweight[18].

Taking into account the high level of inactivity found, it is important to point out that physical exercise is an essential activity in the treatment of diabetes mellitus, thus it has been widely recommended for diabetic patients, since when it is carried out on a frequent basis, it improves glycemic control, reduces cardiovascular risk factors, prevents and slows the development of obesity[2].

This study found that the non-adherence to the drug treatment with oral antidiabetic medications was 77.8%. Investigation about the prevalence of adherence to the pharmacological treatment in diabetic patients has also demonstrated high rates of non-adherence to the treatment, 74% and 86.3%, respectively[19,5].

Regarding the adherence to medications, one noticed that the main reasons for adhering to the treatment were forgetfulness and missing the time to take the medications. The literature has been pointing other aspects involved in the process of non-adherence to oral antidiabetic agents, such as education, occupation, economic level, family relationships, social support groups, stress, among other[5].

Regarding the association between medication adherence and education, in this study there was not a statistically significant relationship. The adherence to the treatment is influenced by the level of knowledge, especially when it comes to glycemic control and to the prevention of complications caused by the disease, since individuals who do not have access to education have difficulty learning and hence higher risk of developing complications[20].

In this context, nurses play a particularly important role in aspects that concern the adherence to the drug treatment, mainly by the direct contact they have with patients. Nurses, due to their presence throughout health services and due to their proximity with patients, become a key factor in the process of education for diabetic people and hence they are facilitators for the adherence to the drug therapy.

Conclusion

Diabetes mellitus type 2 is one of the main public health problems, being one of the most frequent chronic diseases nowadays, which ends up being a challenge for health services, for health professionals and for society. Thus, it is of paramount importance the adherence to the treatment for a proper control of blood glucose levels. However, the non-adherence to oral antidiabetic agents has been noted as a serious public health problem, affecting directly the drug treatment proposed.

It should be noted that in the present study, a large number of patients were considered non-adherent to the treatment with oral antidiabetic medications. In this context, there is a need to expand research on the subject in order to elucidate the mechanisms of adhesion and implement strategies to improve compliance with the prescribed therapy. These actions bring about positive impact on the

quality of life of these patients, since it can improve their glycemic and metabolic profile and reduce the risk of future health problems resulting from complications of diabetes mellitus.

The small sample of this research and the fact that the basic health units have been chosen for convenience characterized the limitations of this study, which may have affected the outcome of the statistical tests. It is recommended that further studies are conducted with larger samples in order to obtain more robust data on the issue of medication adherence among diabetic patients.

Based on these, it raises the importance of the nursing role in the adherence process to the treatment, because nurses have as the essence and specificity of their profession the care to human beings in all their dimensions. Therefore, they are professionals trained to invest in proactive attitudes, able to identify the main barriers of non-adherence, ensuring patients an understanding of the need for treatment, as well as to create activities of adhesion promotion.

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Collaborations

Silva AP contributed to the project design, analysis and interpretation of data, drafting and approval of the final version of the article. Borges BVS, Lira Neto JCG and Avelino FVSD contributed to the analysis and interpretation of data and writing of the article. Damasceno MMC and Freitas RWJF contributed to the project design, relevant critical review of the intellectual content and approval of the final version of the article.

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