Adherence to diabetes *mellitus* treatment and sociodemographic, clinical and metabolic control variables

Adesão ao tratamento do diabetes *mellitus* e variáveis sociodemográficas, clinicas e de controle metabólico

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Keywords
Patient compliance; Diabetes *mellitus*/nursing; Nursing care; Primary care nursing; Primary health care

Descritores
Adesão à medicação; Diabetes *mellitus*/enfermagem; Cuidados de enfermagem; Enfermagem de atenção primária; Atenção primária à saúde

Submitted
December 19, 2014

Accepted
March 4, 2015

Abstract

Objective: To investigate the association between adherence to type 2 diabetes *mellitus* treatment and sociodemographic, clinical and metabolic control variables.

Methods: Cross-sectional study that included 417 diabetes *mellitus* patients. The research instrument was a questionnaire with the study variables; Treatment Adherence Measure; Food Consumption Frequency Questionnaire and International Physical Exercise Questionnaire. Fisher's Exact Test was used to analyze the data.

Results: About 98.3% showed non adherence to the diet, 41.9% to physical exercise and 15.8% to the medication treatment.

Conclusion: No association was found between adherence to type 2 diabetes *mellitus* treatment and sex, age, years of education, length of diagnosis and metabolic control variables.

Resumo

Objetivo: Investigar a associação entre a adesão ao tratamento da diabetes *mellitus* tipo 2 e variáveis sociodemográficas, clínicas e de controle metabólico.

Métodos: Estudo transversal que incluiu 417 pacientes com diabetes *mellitus*. O instrumento de pesquisa foi um questionário contendo as variáveis do estudo; Medida de Adesão ao tratamento; Questionário de Frequência de Consumo Alimentar e Questionário Internacional de Atividade Física. Para análise dos dados utilizou-se o Teste Exato de *Fisher*.

Resultados: Cerca de 98,3% apresentaram não adesão ao plano alimentar, 41,9% à atividade física e 15,8% ao tratamento medicamentoso.

Conclusão: Não houve associação entre a adesão ao tratamento da diabetes *mellitus* tipo 2 e o sexo, idade, anos de estudo, tempo de diagnóstico e as variáveis de controle metabólico.

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DOI
http://dx.doi.org/10.1590/1982-0194201500054

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Conflicts of interest: none to declare.

Introduction

Patients, family members and health professionals have increasingly assumed active roles in the management of diabetes *mellitus* in response to the care demands. To manage the disease, the patients' engagement, the health professionals' training and family and social support are recommended.[1] When the patients face difficulties to assume self-care in the management of their disease, the possibility of not adhering to the recommended treatment is considered.

In this study, non-adherence was considered when the patient's behavior - taking medication, following the diet and making the required lifestyle changes - do not correspond to the recommendations agreed upon with the health professional.[2]

Non-adherence to the treatment of diabetes *mellitus* is a problem whose dimensions are renowned in the international and Brazilian contexts, contributes to the low efficiency level of the treatment with complications in the medium and long-term and, consequently, increases the demand for high-complexity health services.[2-5]

The prevalence of non-adherence shows great variation depending on the study design, research population and measuring method. In the literature, the rates vary between 17% and 86% for medication treatment, 62% to 71% for the diet and 47% to 80% for physical exercise.[6-8]

The evidences show that patients with DM adhere less to the diet and physical exercise than to the medication treatment.[6-8] On the other hand, studies related to non-adherence to the diet and physical exercise remain scarce, as most studies relate to adherence to the medication treatment.[3,6] Studies that investigated the aspects of treatment adherence appoint that cases of non-adherence prevail over adherence cases.[7,9,10]

In a cross-sectional study undertaken in 2010 to investigate adherence and metabolic control in DM patients, out of 423 patients with type 2 DM (DM2) enrolled in 17 Family Health Services (FHS), only six presented adherence to the three recommended treatment pillars - medication, exercise and diet.[9] Based on this study, other research questions emerged, such as: what are the sociodemographic, clinical and metabolic control characteristics of patients who did not adhere to the treatment? Is there a relation between the variables sex, age, education, length of diagnosis and metabolic control and non-adherence?

In view of the complexity of the treatment, the stakeholders in the disease management face a continuing challenge due to the countless variables involved in the treatment adherence.[3,4,8] Knowledge about the variables can support the search for innovative and specific strategies in care delivery to DM patients who do not adhere to the established treatment, as well as enhance the efficacy of the treatment and reduce the demand for high-complexity health services.

The objective in this study was to investigate the association between adherence to type 2 diabetes *mellitus* treatment and sociodemographic, clinical and metabolic control variables.

Methods

A cross-sectional and exploratory study was carried out, involving 417 type 2 diabetes *mellitus* patients, selected through a stratified random sample, in the Southeast of Brazil. Adherence to the three recommended treatment pillars – medication, diet and exercise - was considered. Among the 417 patients, 39 had no body mass index (BMI) records, 33 no abdominal circumference (AC) records, 28 no blood pressure (BP), glycated hemoglobin (HbA1c), total cholesterol (TC), triglyceride (TG) and high-density lipoprotein (HDL) cholesterol records and 56 no low-density lipoprotein cholesterol records.

Four data collection instruments were used: a questionnaire with sociodemographic, clinical and metabolic control variables; the Treatment Adherence Measure (TAM), consisting of seven items to assess the patient's behavior regarding the daily intake of the prescribed medication, on a six-point Likert scale, from 1 (always) to 6 (never); the Food Consumption Frequency

Questionnaire (FCFQ) to assess the consumption of ten food groups according to the number of times the food was consumed in days, weeks and months, and the size of the portions consumed; the International Physical Activity Questionnaire (IPAQ) - short version, consisting of eight questions that assess the level of habitual physical activity, based on information about the frequency, duration of physical activity, as well as the time spent sitting in the week before the interview.[9-13]

To analyze the data, the sociodemographic (age, sex, years of education), clinical (length of diagnosis, body mass index, abdominal circumference, blood pressure, oral antidiabetics, food consumption and physical activity level) and metabolic control variables (glycated hemoglobin, total cholesterol, triglycerides, high-density lipoprotein cholesterol and low-density lipoprotein cholesterol), as well as the MAT and QFCA scores and IPAQ classification.

The reference scores for the analysis were: BMI below 25 kg/m², AC below or equal to 88 cm for women and below or equal to 102 cm for men, systolic blood pressure (SBP) below 130 mmHg and diastolic blood pressure (DBP) below 85 mmHg, glycated hemoglobin (HbA1c) equal or inferior to 6.5%, total cholesterol (TC) inferior to 200mg/dl, triglycerides (TG) inferior to 150mg/dl, high-density lipoprotein cholesterol (HDL) superior to 45mg/dl and low-density lipoprotein cholesterol (LDL) inferior to 100 mg/dl.[12-16] Concerning the dietary consumption, the dietary consumption of 45 to 60% of carbohydrates, saturated fat inferior to 7%, cholesterol inferior to 300mg, protein between 15 and 20%, dietary fibers equal or superior to 20 grams, number of daily meals equal or superior to five was considered appropriate.[16]

To analyze the data from the MAT questionnaire, the scores on each item were added up and divided by the number of items. Scores under five were considered as non-adherence.[11] For the data obtained on the QFCA, the software *Dietsys*, version 4.0, was used to obtain the values related to the quantity of fibers and cholesterol in milligrams and the percentage of carbohydrates, proteins, total fat and saturated fat consumed. Non-adherence was considered as non-compliance with three out of six nutritional recommendations for the nutritional treatment recommended by the American Diabetes Association, which are: daily consumption of total carbohydrates (45 to 60%), dietary fiber (20g or more) and meal fractioning (five to six meals).[12,16] For the IPAQ, the individuals were categorized as: sedentary, insufficiently active, moderately active and highly active. For non-adherence, the patients were categorized as sedentary and insufficiently active.

To describe the sociodemographic, clinical and metabolic control data and the prevalence of non-adherence to the treatment, descriptive analysis was used. To investigate the association between non-adherence to treatment and the variables sex, age, years of education, length of diagnosis and the metabolic control variables, the data were submitted to Fisher's Exact Test. The statistical analyses were developed using the statistical software Statistical Analysis System® 9.0 (SAS). P-values inferior to 0.05 were considered significant.

The study development complied with the Brazilian and international ethical standards for research involving human beings.

Results

Among the 417 (100%) DM2 patients, the women were predominant (66.2%). The mean age was 62.5 (standard error 11.7 years) and the mean length of education 4.2 (standard error 3.5 years). The mean length of diagnosis was 9.0±6.6 years. The majority was overweight, with a mean BMI of 29.3 (standard error 5.3 kg/m²). Most patients (76.3%) presented an altered AC, 77.1% of them women. The mean SBP and DBP were 146.1 (standard error 25.1) and 83.3 (standard error 12.5 mmHg), respectively (Table 1); 69.1% presented altered values, that is, SBP and DBP superior to the reference values.

As regards the medication treatment, 74.6% of the patients used biguanides, 67.6%, sulfonylureas

Table 1. Sociodemographic, clinical and metabolic control variables

Patient characteristics	n(%)	Mean	Standard deviation
Age		62.5	11.7
< 60 years	159(38.1)		
≥ 60 years	258(61.9)		
Years of education		4.2	3.5
≤ 8	352(84.4)		
> 8	65(15.6)		
Length of diagnosis		9.0	6.6
< 10 years	244(58.5)		
≥ 10 years	173(41.5)		
Body Mass Index *		29.3	5.3
Normal	79(20.9)		
Altered	299(79.1)		
Abdominal Circumference †		103.1	11.9
Normal	91(23.7)		
Altered	293(76.3)		
Systolic Blood Pressure ‡		146.1	25.1
Normal	110(28.3)		
Altered	279(71.7)		
Diastolic Blood Pressure‡		83.3	12.5
Normal	220(56.6)		
Altered	169(43.4)		
Total Carbohydrate Consumption		51.8	7.8
Appropriate	287(68.8)		
Inappropriate	130(31.2)		
Saturated fat consumption		7.5	2.3
Appropriate	177(42.4)		
Inappropriate	240(57.6)		
Cholesterol consumption		141.5	71.6
Appropriate	401(96.2)		
Inappropriate	16(3.8)		
Protein consumption		17.0	3.6
Appropriate	212(50.8)		
Inappropriate	205(49.2)		
Dietary fiber consumption		11.5	5.3
Appropriate	28(6.7)		
Inappropriate	389(93.3)		
Number of meals/day		3.9	0.9
Appropriate	22(5.3)		
Inappropriate	395(94.7)		
Glycated Hemoglobin‡		8.2	2.2
Normal	97(24.9)		
Altered	292(75.1)		
Total cholesterol‡		202.6	43.1
Normal	196(50.4)		
Altered	193(49.6)		
Triglycerides‡		206.6	124.8
Normal	155(39.8)		
Altered	234(60.2)		
HDL‡		42.5	12.3
Normal	133(34.2)		
Altered	256(65.8)		
LDL§		120.3	37.7
Normal	112(31.0)		
Altered	249(69.0)		

*28 without records; †33 without records; ‡28 without records; §56 without records

and 4.1 drugs from other classes. Concerning the diet, most patients consumed appropriate quantities of carbohydrates, cholesterol and proteins. Saturated fat consumption exceeded recommendations while dietary fiber remained inferior to the recommended levels. The mean number of daily meals was 3.9 (standard error 0.9). Most patients were classified as moderately active (30%) and highly active (28.1). What the metabolic control is concerned, the majority showed altered values for HbA1c, TG, HDL and LDL (Table 1).

Among the 417 patients investigated, 98.3% did not adhere to the diet, 41.9% to physical exercise and 15.8% to the medication treatment. In the total group of patients investigated, 6.2% did not adhere to the three treatment pillars, 43.6% to two pillars and 34.5% of the patients did not adhere to the diet and physical exercise. In addition, 50.1% did not adhere to a single treatment pillar and 48.4% of the patients did not adhere to the diet.

No association was found between non-adherence to the treatment and the variables sex, age, years of education, length of diagnosis and metabolic control (Tables 2 and 3).

Discussion

The study design did not permit the establishment of causal relations, but the results are relevant from the clinical viewpoint and can contribute to the identification of individual characteristics and clinical aspects of patients refractory to the treatment. The understanding of the phenomenon of non-adherence can sensitize the health professionals regarding what variables are relevant when approaching patients with difficulties to adhere to the treatment. In that sense, these patients demand continuing support to achieve the established disease control targets from the perspective of diabetes education.

In this study, no statistically significant difference was found between the sociodemographic variables and non-adherence to the three treatment pillars. In terms of sex, the results found are in line

Table 2. Selected variables and diabetes *mellitus* treatment pillars

Variables	Medication (n=66)		Diet (n=410)		Physical activity (n=175)	
	n(%)	p-value*	n(%)	p-value*	n(%)	p-value*
Age						
< 60 years	22(33.3)	0.410	156(38.0)	1.000	70(40.0)	0.540
≥ 60 years	44(67.7)		254(62.0)		105(40.0)	
Sex						
Female	42(63.6)	0.671	272(66.3)	0.692	120(68.6)	0.402
Male	24(36.4)		138(33.7)		55(31.4)	
Years of education						
< 4	24(36.4)	0.471	175(42.7)	0.451	74(42.3)	1.000
4 to 8	32(48.5)		172(42.0)		74(42.3)	
> 8	10(15.1)		63(15.4)		27(14.4)	
Length of diagnosis						
< 10 years	39(59.1)	1.000	240(58.5)	1.000	102(58.3)	1.000
≥ 10 years	27(40.9)		170(41.5)		73(41.7)	

*Fisher's Exact Test p<0.05

Table 3. Metabolic control and diabetes *mellitus* treatment pillars

Variables	Medication (n=66)		Diet (n=410)		Physical activity (n=175)	
	n(%)	p-value*	n(%)	p-value*	n(%)	p-value*
Glycated hemoglobin						
Normal	10(15.9)	0.080	96(25.1)	0.685	35(20.8)	0.124
Altered	53(84.1)		286(74.9)		133(79.2)	
Total cholesterol						
Normal	36(57.1)	0.271	191(50.0)	0.449	80(47.6)	0.358
Altered	27(42.9)		191(50.0)		88(52.4)	
Triglycerides						
Normal	21(33.3)	0.264	153(40.1)	0.707	67(39.9)	1.000
Altered	42(66.7)		229(59.9)		101(60.1)	
HDL						
Normal	44(30.2)	0.561	252(34.0)	0.694	111(33.9)	1.000
Altered	19(69.9)		130(66.0)		57(66.1)	
LDL						
Normal	20(33.9)	0.645	110(31.0)	1.000	52(33.8)	0.358
Altered	39(66.1)		245(69.0)		102(62.2)	

*Fisher's Exact Test p<0.05

with the literature, indicating a higher prevalence of women who do not adhere to the medication treatment and physical activity than men, although without significant evidence.[7,8,17] Concerning sex and diet, the results found add evidence to the literature, considering the lack of studies that established this link.[10]

It can be inferred that the predictive variables of non-adherence can take different forms in men and women. Characteristics like low quality of life and socioeconomic level, problems to cope with the disease and higher prevalence of negative feelings are frequently found in women. These factors can represent predictive variables of non-adherence to the treatment.

In terms of age, the studies available in the literature sustain the results found in this research.[10,17] Elderly people display particularities in terms of age that can favor the non-adherence to the treatment. Polypharmacy, related to cognitive problems link forgetting, and physical limitations like visual problems, and even low education and knowledge about the disease are strong predictors of non-adherence to the medication.[3,7]

Despite the countless aggravating factors related to age that can interfere in the non-adherence to the treatment, there is still a lack of studies on the relation between age and physical exercise and diet. The comparative analysis of age and medication adherence available in the literature may not reveal

the extent of the problem. Therefore, future studies can establish the relation between age and adherence to the three treatment pillars, also considering differences in treatment adherence depending on the lifecycle phase. Nevertheless, it should be taken into account that each treatment modality presents peculiarities that can impose different barriers for each age range.

Concerning education, the results found are in line with studies that did not find evidence either based on which the association between education and non-adherence to treatment can be affirmed.[17,18] Education demands attention from researchers and health professionals though. Establishing this link can contribute to the assessment of health service users and to the planning of educative activities in view of the particularities of each learning phase in the lifecycle. If they understand and know about the disease and the treatment, the users will be better able to understand the importance of the recommendations and adhere to the activities the multiprofessional health team has programmed.

What the length of the diagnosis is concerned, as opposed to the results found, other studies show that patients with a shorter length of diagnosis and in the initial phase of the treatment are less adherent to the medication treatment and to self-care in diabetes.[19,20] On the other hand, patients with a longer length of diagnosis may have further information on the disease, making them feel safer and more self-confident towards the proposed treatment.[21]

Over time, treatment compliance can be neglected due to a lack of motivation and perception of effective results, lack of time, absence of family support, comorbidities, cultural issues, among others.[21]

In that sense, health professionals need to double their attention to newly diagnoses patients, with a view to providing them with clarifications about the chronic nature of the disease and the importance of following the treatment regularly. In addition, possible perceptions and beliefs that can compromise treatment compliance and adherence to the health team's recommendations need to be investigated. For patient with a longer length of the diagnosis, the level of motivation and possible limitations that can hamper the adherence to the proposed treatment also need to be assessed.

The analysis of the relation between the metabolic control variables and the non-adherence to the medication treatment, diet and physical activity showed that most non-adherence patients show inappropriate levels of HbA1c, triglycerides, HDL-C and LDL-C. The literature shows that non-adherence to the medication treatment is related to high levels of HbA1c.[20-22] A ten-percent increase in adherence to oral anti-diabetics can lead to an 0.1% drop in HbA1c levels.[23]

Except for randomized clinical trials, lifestyle interventions involving diet and physical activity are complex investigations due to the multiple factors that can interfere in the analysis of the results. A lifestyle intervention study that monitored diabetic users in primary care over 12 months did not find a significant difference in the lipid profile, including triglyceride levels.[23]

Keeping the lipid profile within normal levels is important to prevent the cardiovascular risk. Non-adherence to the treatment does not necessarily represent worse metabolic control. Dyslipidemia results from a complex set of factors that interact mutually and vary depending on the study design, population characteristics, among others.[23]

It can be inferred that the relation between non-adherence to the diet and physical activity and triglyceride levels, as well as the levels of the other lipid variables, need to assessed with caution, considering interference from other factors like the monitoring period, disease stage, complications and comorbidities, other drugs and therapies used in combination, the veracity of self-reporting, among others.[24]

Knowing the population characteristics can provide support in terms of the possible factors that lead DM users to non-adherence behaviors. The factors related to non-adherence differ and take various forms depending on the treatment component and the research population. Studies

with other designs are needed to better understand this theme.

The researchers expect that these study results can contribute to the situational diagnosis of DM users and to the search for innovative strategies to cope with the weaknesses regarding the non-adherence to the three diabetes treatment pillars. This assessment can also constitute a valuable tool to permanently measure the impact of the interventions put in practice.

Conclusion

No statistically significant association was found between non-adherence to the treatment and sex, age, years of education, length of diagnosis and metabolic control variables.

Acknowledgements

Project funded by the São Paulo Research Foundation (FAFESP), process: 2011/04305-5.

Collaborations

Arrelias CCA and Zanetti ML declare that they contributed to the conception of the project, analysis and interpretation of the data. Arrelias CCA; Faria HTG; Teixeira CRS; Santos MA and Zanetti ML declare that they contributed to the writing of the article and relevant critical review of the intellectual content. Santos MA and Zanetti ML declare that they contributed to the final approval of the version for publication.

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