Medical compliance and associated factors in Type 2 Diabetes *Mellitus*

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ABSTRACT

Introduction: type 2 Diabetes *Mellitus* (DM2) is a chronic condition that often goes hand in hand with poor treatment compliance. **Objective:** this study assessed the prevalence of drug treatment compliance and associated factors in people with DM2 assisted by the Family Health Strategy (FHS). **Methods:** this is a cross-sectional observational study conducted in the urban FHS of a medium-sized municipality in Minas Gerais, with a random sample of 190 participants. Two validated instruments were used: the Treatment Adherence Measure (TAM), which assesses the daily use of prescribed medications, and the Batalla test, which assesses adherence through knowledge of DM2. The socioeconomic and clinical profile was collected by a questionnaire prepared by the authors. **Main results:** adherence assessed by TAM (84.2%) contrasted with that estimated by the Batalla test (44.2%). Higher TAM values were significantly associated with polypharmacy (OR=2.7; 95% CI=1.2-6.1). Better adherence by Batalla test was associated with age below 60 years (OR=3.7; 95% CI=1.9-7.1), presence of partner (OR=2.2; 95% CI=1.1-4.1), association of oral antidiabetic to insulin (OR=2.2; 95% CI=1.2-4.0) and compliance with the goal of physical activity (OR=2.6; 95% CI=1.2-5.6). **Conclusion:** the rates of adherence to the daily use of medicines and knowledge about DM2 verified by the study agree with the literature. Worse results in the elderly and those without a partner show a vulnerable group that should receive special attention from health teams.

Keywords: Cooperation and adherence to treatment, Type 2 Diabetes Mellitus, Knowledge, Self-care.

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INTRODUCTION

Type 2 Diabetes (DM2) is a chronic condition whose treatment imposes the reorganization of lifestyle regarding eating habits, physical activity and the use of medications¹. Low adherence to DM2 treatment is a globally recognized problem². The term drug treatment Adherence refers to the extent to which the patient's behavior corresponds to the recommendations prescribed by the health care professional, with regard to the schedules, dosages, and frequency of drug administration³.

Adherence is a determining factor in the course of the disease. Poor adherence increases the risk of complications and costs to the health system⁴⁻⁶. Numerous factors that interfere with adherence have been described. Among the factors associated with low adherence, the following stand out: low socioeconomic level, sedentary lifestyle habits, asymptomatic and chronic disease, complex therapeutic schemes, and inadequate doctor-patient relationship^{4,7}.

On the other hand, diabetes education, better schooling, consolidation of supported self-care and the presence of a support network are pointed out as alternatives that contribute to improving adherence². In this context, the Family Health Strategy (FHS) initiatives for health promotion are perceived as essential.

The WHO emphasizes the need for research on adherence in developing countries as these are the countries where the incidence and prevalence of chronic conditions such as DM2 are expected to increase the most². Thus the aim of this study was to assess adherence to drug therapy and associated factors in DM2 in FHS.

METHOD

This is a cross-sectional observational study conducted in the FHS of the urban area of a medium-sized municipality located in the central-western region of the state of Minas Gerais, Brazil. The study population consisted of 2,978 patients with Diabetes Mellitus (DM) registered in the 32 FHS of the municipality, corresponding to a coverage of 47.4% of the population^{8,9}.

Considering the significance level of 95% and 84.4% as the prevalence of drug adherence found in a study with similar methodology and population^{7,10}, a sample of 190 users was calculated¹⁰.

The participants were selected proportionally to the number of diabetics per health planning region in the urban area of the municipality¹¹. The city is administratively organized in nine areas. Only eight areas had the FHS model for caring.

One FHS in each region was randomly defined. The patients of the FHS chosen were listed and contacted randomly until the sample size of the region was reached. In case of exhaustion of the number of patients, without reaching the minimum expected number, a new FHS was drawn in that region. Eleven FHS were selected.

Participants were recruited between October 2018 and April 2019 and data was collected from November 2018 to May 2019. Active search occurred by telephone contact, in two attempts at different times, whenever necessary.

The home visit occurred on a date and time scheduled within the researchers' availability. In case of inability to contact, schedule incompatibility, or refusal, the search went on to the next participant, in order to ensure that the sample size was contemplated. A total of 2,391 calls were made to select the 190 participants. As a loss, 2,201 users did not participate in the research, 915 due to outdated phone numbers, 1,056 due to non-response to the call, and 230 due to refusal.

The application of the questionnaires was carried out through an interview, after an explanation about the research and the signing of the Free and Informed Consent Term. The pilot project allowed the researchers to refine the questionnaire and its application. Participants who presented classic signs and/or symptoms of hyperglycemia (polyuria, polydipsia, polyphagia, or unintentional weight loss) referred at the time of collection or who had laboratory tests showing lack of good glycemic control, received a report to the FHS describing their case and their need for care without delay. No patient required urgent care.

Inclusion criteria were: being registered in the Health Information System (HIS) of the municipality with DM; having a minimum age of 20 years, corresponding to the age range available in the SIS for stratification of the population with a higher prevalence of DM2. Exclusion criteria were: self-declared diagnosis of Type 1 Diabetes Mellitus or other types of DM and impossibility of telephone contact, time incompatibility, and inability to communicate.

Drug therapy adherence was evaluated using two tests validated for use in Brazil¹²: Treatment Adherence Measurement (TAM) and the Batalla test. The TAM is a tool that assesses adherence to the prescribed drug treatment. To do so, the prescription was checked. It consists of seven questions, answered on a Likert scale ranging from one (always) to six (never). Those participants who obtained a result greater than or equal to five, which corresponds to the average of the answers rarely or never¹³, were considered non-compliant.

The Batalla test measures adherence to drug therapy trhough the participant's knowledge about their condition. It consists of three questions: 1) Is DM a lifelong disease? 2) Can DM be controlled with diet and medication? 3) Name two or more organs affected by DM. 3. name two or more organs affected by DM. Participants who answered all the questions correctly were considered adherent^{12,14}.

The factors associated with adherence were obtained through a structured questionnaire designed by the authors based on a literature review. This is based on the main factors associated with therapeutic adherence, such as: gender, age, marital status, education, time of diagnosis, practice and adherence with recommendations on physical activity, drug therapy, and polypharmacy (daily use of five or more medications)^{4,7,15}.

Physical activity was considered to be any exercise practiced for therapeutic purposes. The minimum recommendation for exercise was 150 minutes per week divided into at least three days¹⁶. Seven self-reported complications of DM2 were investigated: neuropathy, coronary artery disease, retinopathy, acute myocardial infarction, stroke, chronic kidney disease, and non-traumatic amputation.

The participants were categorized according to average household income, using the Brazil Economic Classification Criterion¹⁷.

The association between clinical, care, and socioeconomic conditions (exposure variables), and treatment adherence assessed by the TAM and Batalla test (outcome variables) was performed using Pearson's chi-square test. Categories with a p-value < 0.20 were inserted by the backward method into the multivariate multiple logistic regression model. The Hosmer & Lemeshow test was used to verify the fit of the final model. The odds ratio (OR) with 95% confidence interval (95% CI) was used as a measure of effect. For all analyses, a statistical significance value of 5% (p < 0.05) was adopted. The information was stored in a MSExcel 2016 spreadsheet and analyzed with the support of the Statistical Package for the Social Sciences® version 20.0.

The project was duly approved by the Ethics Committee for Human Research (CAAE: 80092717.7.0000.5545).

RESULTS

Regarding socioeconomic characterization, the study population was composed mostly of women. The mean age was 65.5 years. Approximately two-

thirds of the population lived with a partner, 73.7% studied up to incomplete elementary school, and 58.9% had a mean household income between R\$1,625.00 and R\$2,705.00 (Table 1).

Table 1. Percentage distribution of clinical variables and socio-demographic and economic aspects.

socio-demographic and economic aspects.					
Variables(n = 190)	n (%)				
Female gender	120 (63.2%)				
Male Gender	70 (36.8%)				
Without partner	63 (33.2%)				
With partner	127 (66.8%)				
Education					
Illiterate / Incomplete ES Complete ES or higher	140 (73.7%) 50 (26.3%)				
Average Household Income					
R\$ 768.00	48 (25.3%)				
R\$ 1,625.00 - R\$ 2,705.00	112 (58.9%)				
R\$ 4,852.00 - R\$ 20,888.00	30 (15.8%)				
Physical Activity					
Sedentary	121 (63.7%)				
Not sedentary	69 (36.3%)				
Complies with recommendation	43 (22.6%)				
Does not comply with recommendation	26 (13.7%)				
Smoking					
Never smoked	106 (55.8%)				
Ex-Smoker	66 (34.7%)				
Smoker	18 (9.5%)				
Drinking					
Yes	148 (77.9%)				
No	42 (22.1%)				
Time since Diagnosis					
< 5 yearss	28 (14.7%)				
≥ 5 to < 10 years	57 (30.0%)				
≥ 10 years	105 (55.3%)				
Presence of Complications					
Yes	136 (71.6%)				
No	54 (28.4%)				
Drug Therapy					
OAD only	113 (59.5%)				
Only insulin	18 (9.5%)				
Association OAD+ Insulin					
Does not use drug therapy	54 (28.4%)				
5 (2.6%)					
Polypharmacy					
Yes	137 (72.1%)				
No	53 (27.9%)				

The adherence rate assessed by the TAM was found to be 84.2%, while by the Batalla test the value was 44.2%. About one-third of the respondents were considered adherent by both methods. Among the participants considered adherent by Batalla, 86.9% were also adherent to the TAM, but this association may be due to chance.

According to the TAM evaluation, the main reasons for non-adherence were forgetting to take daily medications and not following the medication schedule. The greatest difficulty presented in Batalla's test was to name at least two organs affected by DM2. Only 50% were able to answer this question correctly.

The main class of OAD used was biguanide, present in the prescription of 82.6% of the participants. On average, 6.17 medications were used per day. Among those in polypharmacy, 66.5% lived with a partner and 63.5% completed elementary school (ES).

As for the DM2 complications surveyed, 70% of the participants had some complication/target organ damage. Neuropathy was the most frequent (48.9%), followed by coronary artery disease (25.2%), retinopathy (20.5%), acute myocardial infarction (10%), stroke (7.9%), chronic kidney disease (7.9%), and non-traumatic amputation (5.3%).

By univariate analysis of the results, only the variable polypharmacy showed a significant association with adherence to drug therapy measured by TAM (Table 2). This association was maintained after multiple logistic regression and allowed us to conclude that participants who presented polypharmacy were 2.7 times more likely to be adherent to drug therapy.

As for the Batalla score, a statistically significant association was found regarding age, marital status, and use of insulin-associated OAD (Table 3). After logistic regression, the variable compliance with physical activity recommendation became significant and the marital status did not hold.

According to the logistic regression performed with the Batalla test, participants aged less than 60 years were 4.4 times more likely to be considered adherent. Those who followed the recommendation of physical activity were 2.6 times more likely to present therapeutic adherence through knowledge. Similarly, participants who associated OAD with insulin were 2.9 times more likely to have a better outcome.

DISCUSSION

This study evaluated the rates of adherence to DM2 drug therapy and its associated factors. Drug

adherence assessed by daily medication use (TAM) was higher than that assessed by DM2 knowledge (Batalla test) (84.2% versus 44.2%). Regular use of prescribed medications was more common in polypharmacy patients. The groups that showed higher diabetes knowledge were those younger than 60 years, with a partner, using OAD and insulin concomitantly, and adherent to the recommendation of physical activity.

The TAM considered 84.2% of the participants to be adherent. National studies, with similar methodology, obtained similar results: 78.3%, 84.4% and 95.7%.^{7,15,18}. In a systematic review, drug therapy adherence values ranged from 36-93%¹⁹. The higher rates of adherence to drug treatment compared to the other therapeutic pillars may be due to the importance given to it by patients and the poorer access to the means necessary for lifestyle changes^{7,15,20}.

The study showed that individuals in polypharmacy tend to be more compliant with drug treatment. The literature diverges on the impact of polypharmacy on adherence^{2,15,21,22}. Although this condition is related to adverse effects and increased frequency of taking medications, it does not necessarily result in worse adherence^{15,21}.

It is noteworthy that among the participants in polypharmacy, complete elementary school education was frequent. This result reinforces the hypothesis that the presence of more education can positively influence adherence^{15,21}. This condition combined with the meaning the patient attributes to drug therapy may motivate him to adhere to the treatment, despite the difficulties inherent to polypharmacy.

Another hypothesis concerns the presence of a greater number of chronic complications resulting from DM2 in patients with polypharmacy. Patients with more severe disease, often symptomatic, would present better rates of adherence in contrast to those with early and asymptomatic disease²¹.

Lower than desired levels of adherence to DM2 knowledge were found (44.2%), in agreement with other studies^{4,27}. The low adherence verified by the Batalla test reflects the lack of knowledge about DM2 among patients^{2,13}. A previous study related low knowledge to few years of schooling and less participation in educational activities, corroborating what was found²⁴. It is alarming that while 70% of the participants had some chronic complication of DM2, only 50% could name at least one target organ of the condition.

Table 2. Association between TAM and clinical variables, sociodemographic and economic aspects.

Variables (n = 190)	Compliant n (%)	Non-Compliant n (%)	OR	(95%)CI	р
Batalla					
Compliant	73 (86.9)	11 (13.1)	1.4	0.6-3.2	0.365
Non-compliant	87 (82.1)	19 (17.9)		1	
Female gender	100 (83.3)	20 (16.7)	0.8	0.4-1.9	0.664
Male Gender	60 (85.7)	10 (14.3)		1	
Age					
< 60 years	44 (81.5)	10 (18.5)	0.7	0.3-1.7	0.516
≥ 60 years	116 (85.3)	20 (14.7)		1	
Without partner	53 (84.1)	10 (15.9)	1.0	1	0.982
With partner	107 (84.3)	20 (15.7)		0.4-2.3	
Education					
Illiterate / Incomplete ES	50 (79.4)	13 (20.6)	1.7	1	0.197
Complete ES or higher	110 (86.6)	17 (13.4)		0.7-3.7	
Average Household Inco-me					
R\$ 768.00 - R\$ 2,705.00	135 (84.4%)	25 (15.6%)	0.9	1	0.886
R\$ 4,852.00 - R\$ 20,888.00	25 (83.3%)	5 (16.7%)		0.3-2.6	
Physical Activity					
Sedentary	100 (82.6)	21 (17.4)	1.4	1	0.433
Not sedentary	60 (87.0)	9 (13.0)		0.6-3.2	
Complies with recommenda-tion	35 (81.4)	8 (18.6)	0.8	0.3-1.9	0.565
Does not comply with recommendation	125 (85.0)	22 (15.0)		1	
Smoking					
Never smoked	88 (83.0)	18 (17.0)	0.9	0.2-3.7	0.974
Ex-Smoker	57 (86.4)	9 (13.6)	1.2	0.3-5.3	0.745
Smoker	15 (83.3)	3 (16.7)		1	
Drinking					
Yes	20 (80)	5 (20)		1	
No	140 (84.8)	25 (15.2)	1.4	0.5-4.1	0.536
Time of Diagnosis					
< 5 years	21 (75)	7 (25)		1	
≥ 5 to < 10 years	8 (14)	49 (86)	2.0	0.7-6.4	0.213
≥ 10 years	90 (85.7)	15 (14.3)	2.0	0.7-5.5	0.175
Presence of Complications					
Yes	11 (85.3)	20 (14.7)	1.3	0.6-3.0	0.516
No	44 (81.5)	10 (18.5)		1	
Uses only OAD					
Yes	99 (87.6)	14 (12.4)	0.5	1	0.119
No	61 (79.2)	16 (20.8)		0.2-1.2	
Uses only insulin					
Yes	14 (77.8)	4 (22.2)	0.6	0.2-2.0	0.431
No	146 (84.9)	26 (15.1)		1	
Polypharmacy	,	. ,			
Yes	121 (88.3)	16 (11.7)	2.7	1.2-6.1	0.012*
No	39 (73.6)	14 (26.4)		1	

ES: Elementary School. OAD: Oral Antidiabetic.

^{*} Variables with statistically significant association.

Table 3. Association between Batalla and clinical variables, sociodemographic and economic aspects.

Variables (n = 190)	Compliant n (%)	Non-Compliant n (%)	OR	(95%)CI	р
Female gender	34 (48.6)	36 (51.4)	0.7	0.4-1.4	0.355
Male Gender	50 (41.7)	70 (58.3)		1	
Age					
< 60 years	36 (66.7)	18 (33.3%)	3.7	1.9-7.1	< 0.001*
≥ 60 years	48 (35.3)	88 (64.7%)		1	
Without partner	20 (31.7)	43 (68.3%)	2.2	1.1-4.1	0.015*
With partner	64 (50.4)	63 (49.6%)		1	
Education					
Illiterate / Incomplete ES	23 (36.5)	40 (63.5%)		1	0.132
Complete ES or higher	61 (48.0)	66 (52.0%)	1.6	0.9-2.988	
Average Household Income					
R\$ 768.00 - R\$ 2,705.00	73 (45.6%)	87 (54.4%)	0.7	1	0.365
R\$ 4,852.00 - R\$ 20,888.00	11 (36.7%)	19 (63.3%)		0.3-1.5	
Physical Activity					
Sedentary	49 (40.5)	72 (59.5)	1.5	0.8-2.7	0.172
Not sedentary	35 (50.7)	34 (49.3)		1	
Complies with recommendation	23 (53.5)	20 (46.5)	1.6	0.8-3.2	0.164
Does not comply with recommenda-tion	61 (41.5)	86 (58.5)		1	
Smoking					
Never smoked	48 (45.3)	58 (54.7)	1.3	0.5-3.6	0.614
Ex-Smoker	29 (43.9)	37 (56.1)	1.2	0.4-3.6	0.701
Smoker	7 (38.9)	11 (61.1)		1	
Drinking					
Yes	15 (60.0)	10 (40.0)		1	
No	69 (41.8)	96 (58.2)	0.5	0.2-1.1	0.088
Time of Diagnosis					
< 5 years	11 (39.3)	17 (60.7)		1	
≥ 5 to < 10 years	23 (40.4)	34 (59.6)	1.0	0.4-2.6	0.925
≥ 10 years	90 (85.7)	15 (14.3)	1.4	0.6-3.3	0.432
Presence of Complications					
Yes	61 (44.9)	75 (55.1)	1.1	0.6-2.1	0.777
No	23 (42.6)	31 (57.4)		1	
Uses only OAD					
Yes	41 (36.3)	72 (63.7)	2.2	1	0.008*
No	43 (55.8)	34 (44.2)		1.2-4.0	
Uses only insulin					
Yes	9 (50.0)	9 (50.0)	1.3	0.5-3.4	0.603
No	75 (43.6)	97 (56.4)		1	
Polypharmacy					
Yes	62 (45.3)	75 (54.7)	1.2	0.6-2.2	0.641
No	22 (41.5)	31 (58.5)		1	

ES: Elementary School. OAD: Oral Antidiabetic.
* Variables with statistically significant association.

Such scarcity of knowledge observed is particularly worrying, considering that the research was conducted exclusively with users of the FHS. It is the role of the FHS to stimulate and promote supported self-care²⁸. The low municipal FHS coverage in the present study may predict an even greater deficit in health education in the municipality as a whole²⁹.

Patients younger than 60 years and living with a partner showed better adherence rates. The negative association of advanced age with knowledge about the disease is described in the literature and is probably explained by cognitive and functional changes prevalent in the elderly, which impair understanding about the disease and its treatment^{22,24}. On the other hand, the presence of a partner represents an incentive for self-care, which may have increased the participants' motivation to learn about their disease and its treatment²¹.

The concomitant administration of OAD and insulin was also associated with greater adherence. The use of insulin in the treatment of DM2, as well as the onset of complications, tends to be delayed depending on good metabolic control¹⁶. Despite the difficulties inherent to the use of insulin, such as the handling for its application and the stigma itself, its use was not a limiting factor for adherence^{2,5}. The presence of more severe and symptomatic disease associated with the length of time living with the condition may once again justify the greater adherence measured through knowledge^{4,7,20,25}.

Regarding the practice of physical activity, the result of the study is also in line with the literature. In the treatment of DM2, lower adherence rates to the diet plan and physical activity are expected compared to the use of medications^{7,16}.

Association was established between compliance with the recommendation of physical activity and adherence by the Batalla test. A previous study showed that participants who overcame the difficulties and implemented physical activity in their routine in the recommended manner developed positive skills and attitudes, which are directly related to the acquisition of knowledge about the disease and self-care⁶.

The absence of a significant association between adherence as assessed by TAM and most of the variables listed was predicted in the literature^{7,23}. The lack of association with the Batalla test reinforces the hypothesis that knowledge is insufficient to sustain adherence, which is also linked to psychosocial factors²⁴.

Studies show difficulty in measuring adherence even by the best instruments currently available¹². The TAM, for example, is an instrument based on self-declaration and depends on the veracity of the information provided, a limitation of the study.

Another obstacle is measuring the impact of all aspects that interfere with adherence in a cross-sectional study. The methodological characteristic does not provide data on the incidence of drug adherence, nor cause and effect associations in the analyses performed^{18,25,26}.

Among the limitations of the study, the absence of analysis of glycated hemoglobin levels makes it impossible to perform laboratory verification of glycemic target adherence. Adherence refers to the use of medication within a limited period of time. The methodology adopted prevents the evaluation of the levels of persistence to treatment, despite the levels of adherence.

CONCLUSION

This study identifies weaknesses in adherence to DM2 drug treatment in users of FHSs and delimits subpopulations whose approach would cause greater impact. The elderly population and those without a partner, in particular, deserve individual and group educational approaches with the construction of a unique therapeutic plan and strengthening of supported self-care.

The application of instruments validated and translated into Portuguese makes the findings of the present study comparable to the literature on the subject. The previous training of the researchers in the field and a pilot project demonstrate methodological care and confer reliability to the results. The present study shows a local reality with adherence that is less than desirable, whether in the declaration of medication use or in knowledge about diabetes. Given this scenario, we intend to encourage targeted interventions and the measurement of their impact.

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- 1. Project elaboration: FZB, KJF, BABS, GFN, MMD, AAM.
- 2. Data collection: FZB, KJF, BABS, GFN, MMD.
- 3. Data analysis: DNC.
- 4. Article Writing: FZB, KJF, BABS, GFN, MMD.
- 5. Critical review: AAM, DNC.

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