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Adherence to therapeuthic regimen and metabolic control of type 1 diabetes

Madalena Cunha[a],*, **Ana Paula Matos**[b], **Vera Almeida**[c], **Carlos Albuquerque**[a], **António Madureira**[a], **Estudantes 28ºCLE**[a]

[a] *Instituto Politécnico de Viseu, Escola Superior de Saúde, CI&DETS, Viseu, Portugal*
[b] *Universidade de Coimbra, Coimbra, Portugal*
[c] *Instituto Superior de Ciências da Saúde do Norte*

KEYWORDS
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Abstract

Objectives: To assess the adherence to therapeutic regimen; to determine the Hemoglobin Glycation Index (HbA1c); to analyse the relationship that exists between the adherence to therapeutic regimen and metabolic control.

Design: correlational analytical study, carried out according to a cross-sectional perspective.

Participants: A non-probabilistic sample of 266 people with type 1 diabetes aged between 18 and 78 years old (mean M = 51.02 ± SD = 18.710), attending follow-up diabetes consultations. Mostly male individuals (51.88%), with low schooling level (50.75% had only finished elementar school).

Measuring Instruments: We used the following data collection tools: a questionnaire on clinical and socio-demographic data, blood analysis of venous blood to determine the glycated hemoglobin level (HbA1c). Three self-report scales were used: Accession to Diabetes Treatment (Matos, 1999), Self-perception Scale (Vaz Serra, 1986) and Social Support Scale (Matos & Rodrigues, 2000).

Results: In a sample in which the mean disease duration is 12.75 years, 69.17% of the sample run glycemic control tests between once a day and four times a year and 42.86% of them undergo insulin treatment. In the last 3 weeks, 26.32% of these people have experienced an average of 4.22 to 44.36%, hypoglycemic crises and experienced an average of 6.18 hyperglycemic crises. 57% of the individuals have showed a poor metabolic control (mean HbA1c higher than 7.5% (HbA1c mean M ≥ 7.50%).

The mean psychosocial profile revealed individuals who show a decent self-esteem (M = 70.81) and acceptable social support (M = 58.89).

Conclusions: The results suggest we should develop a kind of investigation that could be used to monitor the strenght of the mediation effect effect of the psychosocial predictive dimension of the adherence, since it has become essential to support a multidisciplinary approach which center lays in the promotion of a co-responsible self-management from the person who suffers from diabetes. This will enable a better quality of life; fewer years of people's lives lost prematurely and a better health with less economical costs for citizens and healthcare systems.

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*Corresponding author.
E-mail: madalenacunhanunes@gmail.com (M. Cunha).

Introduction

In Portugal chronic non-communicable diseases, of which diabetes is part, are one of the biggest challenges to people's health. These types of condition represent the highest percentage among all the diseases, the general population's main causes of death and the main cause of death for people aged between 30 and 69 years old.[1] In 2014 diabetes killed 4,9 million people worldwide (50% of them were below 60).[2] According to some predictions for 2035, the number of diabetic cases could increase up to 592 million, which will represent a 55% growth of people diagnosed with diabetes.[2,3] Data from the Annual Report of the National Diabetes Observatory and from the World Health Organization reveal that Portugal is among the European countries who show a higher prevalence of diabetes.[3] According to data from 2013, the total estimated prevalence in the 20-79 age-group was 13%.[3] The predictions made about Portugal show that in 2014 the cases of diabetes could rise to about 1042 (in every 100 thousand inhabitants) and that around 354 of those cases (in 100 thousnad inhabitants) haven't been diagnosed yet.[2] Diabetes has a higher incidence in male patients than in female individuals (15.6% and 10.7%, respectively) and there is a direct correlation with the fact that the population is getting older and older.[2,3]

Therefore, to discuss the adherence to a therapeutic regimen in diabetes is particularly pertinent because it is a chronic, epidemiologically relevant disease, in which the patient's involvement and participation is not only important to his quality of life, but is crucial for his survival. When people don't follow the prescribed treatment, this can lead to physical complications which in the short and long-term will generate the destruction of the tissues, damage systems, prevent people from performing usual functions and even lead to death.

Type1 diabetes is a chronic disease which causes the destruction of the beta cells of the pancreatic islets of Langerhans. This condition can be inherited, acquired or caused by an organic incapacity.[4] It's a metabolic disorder of multiple etiology, characterized by a chronic hyperglycemia with an abnormal increase in the blood glucose levels.[5]

Type 1 diabetes is caused by absolute insulin deficiency and because of that insulin therapy is essential to the patients' survival.[4] Since patients with type1 diabetes are absolutely dependent on exogenous insulin replacement, the treatment is essentially done through daily insulin administration via syringe or a pen with needle and cartridge, several times a day, normally before meals. This treatment requires patients to check their blood sugar level when they take insulin and whenever there's evidence of a significant decrease in the blood sugar levels (hypoglycaemia) because ofan increase in physical activity or a descrease in the comsumption of carbohydrates, for instance.[4]

Although the administration of exogenous insulin will keep the level level of glucose within a normal range during the therapeutics periods that have been defined, there is no cure for this pathology and its long-term complications may cause serious incapacities and a reduction of patients' average life expectancy.[6]

The metabolic control of diabetes is defined as a way of achieving a normal concentration of glucose in the patients' blood. It is a biological variable which measurement can be performed in a laboratory through the analysis of glycated hemoglobin, or at home through the monitorization of the blood sugar level. The measurement of glycated hemoglobin is used both in clinical practice and in medical investigation to assess metabolic control, since its study gives information about the "balance" achieved in the quality of the diabetic control for the last 60-90 days since it will reflect the concentration of mean glycaemia during this period of time. Glycated Hemoglobin Values A1c (HbA1c) ≥ 6.5% show a bad metabolic control.[4]

Diabetes is a disease that, when it is not conviniently controlled, can have very negative immediate or irreversible implications. That is why this condition requires different levels of efforts from the people who suffer from it in order to prevent the disease from becoming even more serious or to prevent the emergence of other associated diseases which will jeopardise their quality of life.[6,7] A suitable management of diabetes requires a thorough adherence to a daily treatment. "Adherence" is seen as a *"self-initiated action to promote one's well-being, recovery and rehabilitation by unconditionally following the orientations that had been defined and by showing a total commitment to a set of actions and/ or behaviours*[8]. *The patient follows the treatment regimen, takes his medication as it was prescribed, changes his behavior for the better, looks for medication at the right time, becomes aware of the importance of following a healthy behaviour and obey the rules defined for the treatment"*.[8]

On the other hand, a non-adherence position means not following or not agreeing with the treatment regímen. Adherence to the therapeutic regimen is an active and responsible self-care process. It requires the execution of a complex range of behaviours, like starting and maintaining a treatment programme (food, physical exercise and therapeutics), regular control consultations and a willingness to undergo therapeutics.[9]

The evaluation of the compliance to the therapeutic regimen depends on the context, methods and the predefined criteria (self-reporting, behavioural measures, analytical indicators and therapeutic results).[10] In the case of a chonic disease like diabetes, to evaluate the adherence or compliance to treatment requires to measure how each patient performes each component of the prescribed treatment and, from there, use a set of criteria to classify those who showed compliance and those who didn't.[10]

Considering that the person-centered intervention and the person's capacity became the new paradigm focus that will guide current health interventions, healthcare professionals have, nowadays, to adopt strategies that will maximize people's self-management capacities and help them accept the therapeutical regimen.[6,10,11]

The need to understand and explain the existence of a significant prevalence of people with diabetes who don't adhere to treatment, who are reluctant to undergo therapy or who are metabolically unbalanced are the main justifications to the development of this study for which the following objectives were established: to assess the adherence to a therapeutic regimen; to determine the Hemoglobin Glycation Index (HbA1c); to analize the relationship that exists between the adherence to a therapeutic regimen and the metabolic control.

Material and methods

Type of study

Descriptive, cross-sectional study composed of 266 people suffering from Type 1 diabetes, aged between 18 and 78 (mean age M = 51.02 years ± 18.710 SD), living in central and northern regions of Portugal (Fig. 1).
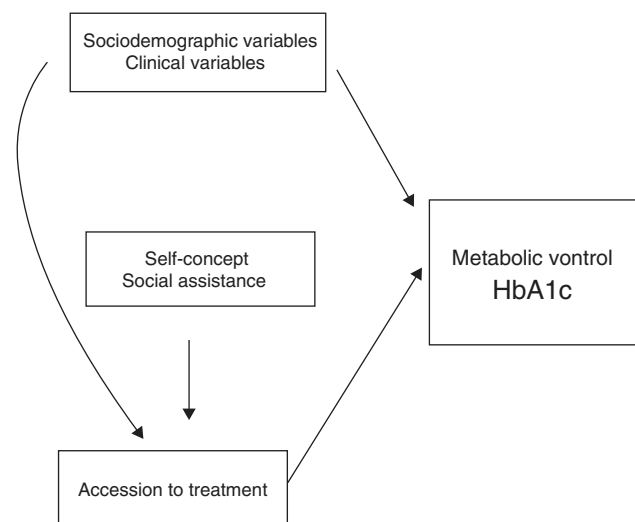

Figure 1 Design of the study.

Participants

The non-probabilistic sampling was composed of 266 participants (51.88% men) who had volunteered to complete the questionnaire and accepted to be measured and weighed.

Those are the inclusion criteria that were considered for the sample's participant selection: people suffering from type1 diabetes who are attending follow-up diabetes consultations, people who are over 18 and who don't have any other potential chronic disease.

Data collection instrument

Data collection was conducted through a questionnaire which was used to obtain information about sociodemographic and clinical aspects of the participants and which included a record of HbA1c values determined through venous blood analysis; Calculation of the Body Mass Index, through body weight (kg) and height (cm) evaluation. Three self-report scales were used: Adesão ao Tratamento da Diabetes (Matos, 1999),[12] Inventário de Autoconceito (Vaz Serra, 1986)[13] and Escala de Apoio Social (Matos & Rodrigues, 2000).[14]

Ethical, legal, and statistical procedures

Before collecting the data, permission was obtained from the HST Ethics Committee. After that, the authors requested permission to use the Data Collection Instrument, which was also granted. Data collection was authorized by the Responsible bodies of the institutions. Later we contacted each participant personally and provided him with an Informed Consent Form in which detailed information was offered about the study and confidentiality was assured. The statistical analysis of data was performed with SATA Programme (version 6.0 for windows).

Results

Diabetes Mellitus Type 1 diagnosis occurred on average when patients were 12.75 years old. 49.62% of those patients suffered on average 3.15 hospitalizations caused by diabetes. The results used to create their clinical profile show that:

— Glycaemic control was performed in 69.17% of the patients once a day to four times a year and 31.52% only performed this self-care twice a day. Only 42.86% of the patients followed properly the insulin treatment and 51.13% took insulin twice a day.
— Poor metabolic control (HbA1c mean ≥ 7.50%) affected 57.52% of those people.
— 26.32% of the individuals suffered, on average, 22 hypoglycaemia crisis in the last 3 weeks and 44.36% suffered an average of 6.18 hyperglycaemia crisis in the last 3 weeks which shows their poor glycaemic control.
— 60.15% followed a normal food pattern, except for the ingestion of refined sugar (once to four times a month), 51.88% didn't do any physical exercise and 44.74 were overweight (BMI, M = 26.07).
— Complications caused by diabetes were seen in 38.35% of the people: the most frequent were retinopathy (84.31%), neuropathy (31.32%), foot problems (29.41%), heart disease (21.56%) and nephropathy (11.56%).

Adherence to therapeutic regimen

The mean value of accession from people with diabetes was 79.49 ± 17.104 (with a 26.00 minimum and a 125.00 maximum). Men (80.97 ± 17.207) showed a higher participation than women (77.89 ± 16.914).

Influence of sociodemographic variables in the adherence to a therapeutic regimen
The correlation between age and adherence (r Pearson = –0.326; P = .000) showed that the older people are, the lower the adherence to a therapeutic regimen. The results obtained regarding the age-group also suggested that younger people, aged between 18 and 53 (n = 134; 50.38%), show a higher participation in these regimens than older people whose age ranges from 54 to 78 (n = 132; 9.62%). The significant differences detected are (82.73 ± 16.830; 77.19 ± 16.809; t = 3.168; P = .001).

The analysis of the variation done to explore the relationship between adherence and patients' marital status and level of education showed the existence of significant statistical relationships. Widows with diabetes show a higher rate of participation in the therapeutic regimen than married or single female patients. Married patients (M = 76.10) show a higher adherence level than widowers (M = 93.41;

Tuckey *P* = .000) and single male patients (M = 87.07); (F = 14.151; *P* = .000; Tuckey *P* = .002). Participation in the regimen was more evident in people with a higher level of education. There is a significant difference between the participation of patients who graduated from high-school (M = 90.84) and illiterate patients (M = 71.32; *P* = .000), patients who have only finished primary school (M = 78.58; *P* = .005) or elementary school (M = 82.69; *P* = .005); (F = 6.374; *P* = .000).

Influence of clinical variables in adherence
to a therapeutic regimen
Globally, people with diabetes who have been living with the disease for a longer period of time are those who show a poorer participation in the therapeutic regimen (r = –0.151; *P* = .013). In contrast, those who went through periods of hospitalization show a higher adherence (t = –2.368; *P* = .018).

Patients' participation in this kind of regimen has a negative relationship with glycated hemogloblin (HbA1c) (r = 0.137; *P* = .026): the higher the participation, the lower are the hemoglobin values and the better is the glycaemia control.

People with diabetes who suffered from hypoglycaemia had lower participation levels (M = 77.30 vs M = 85.60) than those who had never experienced this kind of complication (F = 12.661; *P* = .000).

Influence of the psychosocial variables (self-concept and social support) in adherence to a therapeutical regimen

The average psychosocial profile revealed a decent self-concept (M = 70.81; SD = 15.216) and social support (M = 58.89; SD = 11.616). Adherence seems to have a positive and hugely significant relationship with self-concept (r = 0.532; *P* = .000) and with social support (r = 0.382; *P* = .000), informational support (factor 1) (r = 0.499; *P* = .000), emotional support (factor 2) (r = 0.127; *P* = .039) and instrumental support (factor 3) (r = 0.192; *P* = .002). In this perspective it will be logical to accept that a higher willingness to join such regimen corresponds to a better social, informational, emotional and instrumental support.

Level of adherence to the therapeutic regimen

Keeping in mind the median values of the "adherence to a therapeutic regimen" value, we concluded that the majority of people with diabetes (76.79%) had reported a poor adherence and that only 23.31% of them refer a good adherence. We found out the existence of significant differences in the mean values of the psychosocial variables when we compared people with diabetes from the two groups (poor adherence versus good adherence). In other words, the participants who showed a higher adherence also showed more social support and a higher self-concept than those who reported a poor adherence.

Discussion

The participants in this study are mainly men with low functional literacy (primary school). This result deserves to be analysed since the socio-demographic variables had a direct and a statistically significant influence on the adherence to the therapeutic regimen.

The functional literacy changes the patients' behaviours in a highly positive way when it comes to the control and execution of the capillary glycaemia.[10,15] Proper literacy levels seem to lead to health improvements and a better quality of life. On the other hand, lower literacy levels are associated with poor health and, consequently, to a higher mortality rate.[2,16]

In the same context, the results obtained in this study show that patients' school level has a significant relationship with adherence and evidence was that individuals who had successfully concluded high-school have a higher participation in this kind of regimens.

People who are older and people who have been suffering from diabetes for a long time are less prone to participate in these regimens, (people with diabetes for more than 10 years showed a lower adherence to the treatment). This suggests that younger people have better adherence behaviours. With the experience/ teachings/information that the patient has obtained while living with the illness, the therapeutic adherence will have a greater impact on the self-management of the disease.[17]

As far as the metabolic control is concerned, we had collected significant statistically values. These values showed us that the higher the adherence to therapeutic regimen, the lower the values of glycated hemoglobin and the better the metabolic control showed by those patients. People with diabetes that have experienced hospitalizations show a higher adherence. The results we have obtained are in agreement with those published in other studies,[18] in which evidence showed that the socio-demographic and clinical variables defined for people with type1 diabetes interfered statistically with the willingness to participate in the therapeutic regimen. Younger patients and women showed a higher adherence and a better glycaemia control.

Adherence to a therapeutic regimen is a protection against the emergence of chronic complications caused by diabetes[19] and represents a clinically relevant indicator. The results of this study also show that adherence is higher in the patients who don't have complications.

The previous evidence confirms the idea that social support is an important determiner of how the chronic disease can be managed by the patients. The results obtained in this investigation also show that a better social, informational, emotional and instrumental support will lead to a higher adherence to a therapeutic regimen, which is highly significant in this group of people. Considering that the central issue in debates about diabetes has been the behavioural adaptation to a chronic state of the disease,[20] the evaluation of the psychosocial behaviour of the person with diabetes and the way he will be able to self-manage the disease become crucial.

As far as self-concept is concerned, we concluded that there is a higher adherence when there is an increase in the self-esteem and self-concept ratings. This shows that the self-efficiency factor is predictor of a better participation in any therapeutic regimen. These results are in agreement with what is documented in the scientific literature.[7,11,20]

Adherence to therapeutic regimen has proved to be predictive of the Glycaemic/metabolic control, that is, the

more the person believes in the treatment, the more she wants to participate in it, the lower is her glycated hemoglobin level and the better is her metabolic control. The results presented show that the psychosocial variables we have studied favour healthy behaviours and thus can be used to justify preventive and therapeutic guidelines that have to be implemented in the healthcare provided to people with type 1 diabetes.

To be able to positively manage diabetes means to experience and to live new challenges. We will have to guide people with diabetes who show false beliefs, little knowledge of the disease and a poor adherence to a therapeutic regimen so they can seek personalized therapeutic help and attend follow-up consultations with a specialized healthcare professional. This strategy will improve clinical performances that will hopefully lead to a longer and healthier life. A bigger investment in the scientific research that deals with this often neglected issue may lead to the discovery of new clues that will surely help people with diabetes live with a better quality of life.

What we know about the theme

Substantial empirical evidence shows that there is a relationship between adherence to regimen and metabolic control in diabetes. Adherence to a therapeutical regime is considered as a mediator in health gains that can significantly influences people's quality of life and life expectancy.

What we get out the study

— The study shows that adherence to the therapeutic regimen was associated with metabolic control in people with diabetes.
— In other words, the participants with a higher adherence rate showed lower HbA1c values. This fact leads to a better metabolic control.
— Keeping these results in mind when implementing monitoring and preventive interventions can be a great opportunity to achieve a better health promotion and protection. These achievements will surely have great relevance in public health.
— The results suggest that we should develop a kind of investigation that will be used to monitor the strength of the mediator effect of the psychosocial predictive dimensions of adherence, since it is essential to support a multidisciplinary approach centered in the promotion of a co-responsible self-management of the person with diabetes. The partnership taht has to be established in the management of the disease involves experienced healthcare professionals that will help improve the way patients feel about their lives, help reduce death rates and improve the patients' health and reduce the economic costs heathcare has for citizens and for heathcare systems.

Conflict of interests

Participants were volunteers.
The authors declare that there are no conflicts of interests.

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