Diabetics' Adherence to Medical Treatment/Self-Monitoring Program- A Pilot Study

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Abstract

Background: Diabetes is a major problem of public health through its personal and social dimensions. The treatment of diabetes associated with lifestyle modification and monitoring of laboratory parameters will lead to decrease diabetes complications and associated costs.

Aim & Objectives: The purpose of the present study is to describe the profile of the diabetic patient in Romania, studying the adherence of treatment and self-monitoring of diabetics.

Methods/Study Design: This research is a cross-sectional study, carried out in 2011, February-April.We included in the study a number 477 patients from 10 GPs (Bucharest and Ilfov County) who agreed to cooperate. We colected data from two questionnaires (demographic, diabetes status, self-management activities) and from GPs evidence (treatment, co-morbidities, BMI, blood pressure, lipid profile, HbA1c level).

Results/Findings: More type 2 diabetics had other diseases than type 1 diabetcs ($p<0,001$) because they are older persons. Over 2/3 of the patients declare to have a good adherence to the medication but the majority had a poor control of the glycaemia (HbA1c level). The HbA1c value differences were non-significant between type 1 and type 2 diabetics. Complications score was highly correlated with HbA1c value and with adherence to the treatment. The strongest factor related with a better HbA1c value is, as expected, the special diet for diabetics ($p=0,021$).

Conclusion: The average HbA1c is over what is considered as adequate and, obviously, the number and the extent of complications, high, in spite of the declared good coping with the medication program. A better and closer follow up and monitoring of diabetic patients, a tighter schedule of consultations with the GP and specialist, the onset of a program of support carried out by trained nurses could be answers to serious inadequate behaviors..

Key words: HbA1c level, type 1 diabetes, type 2 diabetes, medical adherence, self-monitoring of diabetics

Introduction

Diabetes is a serious condition that became a major public health concern in recent years due to its alarming increase in morbidity. Incidence of type 2 diabetes is closely correlated with that of obesity. Type 1 diabetes is on a slower but steady rising trend, with variations around the world, explained by different factors (environment, genetics, ethnicity etc). [1] Diabetes is a complex illness, requesting a high level of cooperation and self-management from patients. Comprehensive treatment is composed of lifestyle modifications; pharmacological control of hyperglycemia, high blood pressure (BP), and hyperlipidemia; and preventive care such as monitoring for glycemic control.[2] As easy as it might sound, putting in practice thorough changes of lifestyle is often more difficult than following a complex program of medication. Modifying lifestyle, particularly dietary and exercising habits, are necessary for all the diabetic patients but are difficult to carry out. [3]

Diabetics have to cope with two burdens, medication and a complex plan consisting of an everyday self-care plan. Sticking with a rather complex schedule of medication and lifestyle changes is seriously challenging, but essential in maintaining a normal glycemia, which is the key to a long and complication-free life. The level of glycemia has long been recognized as being by far the most important factor in preventing complications of diabetes The DCCT (Diabetes Control and Complications Research Group) trial provided strong evidence for type-1 diabetes [4] and the United Kingdom Prospective Diabetes Study, for patients with type-2 diabetes. [5-9] The American Diabetes Association publishes standards of care every year to make public the importance of achieving optimal glycemic control (glycated hemoglobin - HbA_{1c} <7%).[10] Many studies have shown that lifestyle changes are perceived as problematic and very difficult to adhere to on a daily basis, but when implemented, are an essential benefic factor in diabetes evolution.[11-13] Reported figures might differ from a study to another, but it is generally known that almost half of the diabetic patients are non-adherent to medication and lifestyle changes.[14] Elderly diabetics can find the usual constraints even more difficult or impossible to be regularly applied, compared to younger patients. [15]

In Romania, the incidence of diabetes, as reported by diabetes specialists, increased from 59/100.000, in 1991, to 334/100.000, in 2010 and 358/100.000 in 2011.[16] Within this framework, the Romanian Ministry of Health started a national program for diabetes some years ago, aiming at the prophylaxis, the early detection and the management of diabetes. The program establishes the roles played by all the parties involved in diabetes management and treatment, from specialists, to general practitioners. However, as figures from the National Institute of Public Health show, the problem of diabetes in Romania is far from being solved or at least mitigated and the morbidity is still on the rise, requiring more effective intervention strategies. The present study aims to profile the diabetic patients in Romania, in order to find most important problems, to figure out their solution and to draw conclusions on how to address them properly.

Materials and Methods

The present cross sectional study was carried out in 2011 on a sample of 477 patients. The patients were selected randomly from the diabetic patients of 10 general practitioners (GPs) from Bucharest and Ilfov County, during the month of February.

The practitioners were approached previously during a medical conference and agreed to cooperate. After the initial selection, all subjects under the age of 18 or those who have not visited the general practitioner during the last 12 month were dropped, as new clinical and biochemical parameters could not be produced. Thus, the resulting sample had 692 patients. Each was subsequently contacted by mail, phone or during a routine medical visitation, was familiarized with the purpose of the study and asked for participation. Only 477 patients accepted to be included in the study and were summoned to the GP`s cabinet during the month of March or April. During the meeting, the patients were familiarized again with the purpose and stages of the study, were allowed to ask questions about the study and then were required to complete the Consent Form approved by the Institute's Ethical Committee. At the same meeting, they had to complete two questionnaires. The first was a comprehensive questionnaire gathering demographics and some items linked to the disease (age of onset, duration of the disease, compliance with the treatment). The second aimed the self-management activities. We used the revised version of the Summary of Diabetes Self-Care Activities (SDSCA).[17] The SDSCA is considered a reliable, valid, and multidimensional measure of diabetes self-management behaviors based on self-report. We asked the respondents to complete it with the average number of days of different activities carried out in the prior week (dieting, exercising, smoking, etc.) and the number of days was considered as a score for the specific item involved in the evaluation.

Different other parameters were taken from the personal files of the patients or were measured during the scheduled meeting. They included height and weight (from which BMI was calculated), blood pressure (BP) and the lipid profile. GPs provided data for the current treatment, the eventual existence of diabetes complications and of other co-morbidities. A complications score was calculated, by means of Diabetes Complications Severity Index (DCSI), divided by the number of complications categories (e. g retinopathy, nephropathy neuropathy, cerebrovascular, cardiovascular, metabolic, peripheral vascular disease), The higher score is the reflection of more numerous and severe complications.

As for the glycemic management, we used the level of glycated hemoglobin (HbA1c), as a marker for the average plasma glucose over the previous 8 to 12 weeks. HbA1 c is considered the best test for assessing glycemic control in people with diabetes.[18,19] Usually, HbA1c can be carried out at any time of the day, not requiring peculiar preparation of the patient such as fasting. Though the WHO recommends the 6.5 value for diabetes diagnoses, we selected a slightly higher value since we had already diagnosed patients, followed in their evolution. The cut-off point for desirable HbA1c was considered 7, as many studies show that above this level the incidence of complications rises significantly. [19, 20, 21-24]

Statistical software package SPSS for Windows version 13.0 (SPSS, Chicago) was used for analyses. We started with a descriptive analysis of data. In the descriptive analysis, since none of the continuous variables met the normal distribution criteria, median values were used instead of mean. Non-parametric tests were applied for groups comparison (Kruskal Wallis, Man Whitney), as well as Spearman rho, for correlations. Binary logistic regression was used, with desirable/non

desirable HbA1c values as dependent variable and different others items from the questionnaire, as determinants. In order to explore natural groupings (or clusters) within the diabetics group, a two-step cluster analysis was chosen, applying the Schwarz`s Bayesian Criterion, taking in account as categorical variable, the adherence to prescribed drugs and the diabetes type and as continuous variables, the self-management scores, the values of BP, cholesterol (Total and High Density Lipoprotein – HDL), triglycerides (TGG), HbA1c and age. Significance was attributed to scores with p<= .05.

Results

Of all subjects, 32,1% had type 1 diabetes, all of them taking insulin and 67, 9% had type 2, from which 46, 7% were undergoing treatment with insulin. From the sample, 4% of the type 1 and 14, 5 % of the type 2 used both insulin, and oral anti-diabetics.

Type 2 diabetics had more co-morbidities (diabetes complications excluded), than type 1, hence being poly medicated (Mann - Whitney U=1249.5, p< .001).

One explanation of the finding might be the age of the patients (type 2 are older patients), with the initial significant correlation between the type of diabetes and the number of prescribed medicines (p<. 001) becoming non-significant, after correcting for age (p= .566).

The usual medication plan for the patients included, apart from oral anti diabetics and/or insulin, anti-hypertensive drugs and hypo-cholesterolemiants.

The adherence to the treatment was evaluated from the answers given to the questionnaires and classified in two categories: 1 = low adherence; 2 = high adherence. Taking in account that medicines involved are totally free or partially compensated by the Health Insurance System, the answers were presumed to be more accurate than biased. The adherence seams not to be influenced by the number of drugs prescribed, the correlation between the two variables being non-significant. (Spearman rho=.-122, p=.129). Over 2/3 of the patients declared to have a good adherence to the medication.

The majority of the sample had a poor control of the glycemia, evaluated by means of the HbA1c value (8.7 ±2.3; median 8.2). The value did not correlate significantly with the type of diabetes, age, age of onset or length of the disease, when correcting for medical adherence, but independently correlated with medical adherence. There is a small and non-significant difference of the control in favor of type 1 patients, caused, probably, by the better (yet not statistically observed) adherence to the medical treatment and by the better self-management. The average BP (both diastolic, and systolic) are better for type 1 diabetics, patients showing also a better lipid profile and a median BMI in the range of normality

Using the complications score, the study showed that only 33.3% of the patients were free of any complications and 21.5 % had just a minor one. The finding is obvious, in the perspective of the poor glycemic control. Apart from eye and renal complications, most frequent were peripheral obliterative arteriopathy and peripheral neuropathy. Complications score was highly correlated with HbA1c value (R= .305) and with adherence to the treatment (R=-.362). It is

important to stress out that even though type 1 diabetics lived with the disease far longer than type 2 diabetics, the difference in complications score is non-significant between the two categories of patients. In a twice shorter period of time, the type 2 patients reach a high score of complications. The HbA1c value differences were non-significant between type 1 and type 2 diabetics, but unfortunately we had not the dynamic values registered through time and we could only assume that, probably, the glycemic control was better for type 1 than for type 2. (table 1)

Further on, we investigated the adherence to the self-care plan and its influence on glycemic control (table 2). As already emphasized, diabetes management requires self-care and deep lifestyle changes. The importance of the self-care has been many times emphasized in different types of studies. Apart of coping with a rather comprehensive drug plan, the diabetic patient has to comply with a special diet and exercising plan and has to test his glycemia as indicated by health care providers. Indications may differ between the two types of diabetes, especially regarding the frequency of the glycemia measurements. Recently, in the self-management evaluation, two other items were added: foot care and cigarette smoking. Smoking is not directly influencing diabetes evolution, but it remains a major hazard for cardio-vascular diseases, especially for diabetic patients. [25] In table 2, we present the average days in which patients get involved in self-management practices during the previous week (SDSCA questionnaire results) and the percentage of smokers. The number of days have been considered as scores, and thus a higher number of days were transposed as higher scores.

Some differences are not significant, since obviously type 1 diabetics have to test more frequently glycemia than type 2. As a whole, results are better for type 1 diabetics, some of the differences being probably due to their median younger age. However, the level of physical activity is very low. The entire group of diabetics seems to live a very sedentary life, with days when not even ½ hour per day is dedicated to physical activity and with less than a day per week having time dedicated to a more intense and organized plan of exercising. The importance of exercising in diabetes has been stressed out in many studies. Frequently, regular exercising allows the reduction of anti-diabetic agents and special exercises were designed for different situations, even for elderly patients or patients with diabetes complications. [26]

Coping with the specific diet for diabetes (with counted carbohydrates) seems to be widespread. Unfortunately, the intake of vegetables and avoidance of fat-rich animal foods are not regular habits. A reasonable dietetic approach in groups with diabetes but also with high cardiovascular and obesity risks has to include not only the classic diet plan with carbohydrates counting, but also a thorough change of eating habits, in order to provide an adequate background for avoidance of co-morbid conditions.[27] Considering the above findings, it is clear that a closer attention has to be paid in educating and monitoring daily habits of diabetic patients. This can be done in GP`s office and/or at home, with a close supervision of a certified nurse, as other studies show. [28, 29]

The figures (considered as separate scores) from the SCDSA questionnaire were correlated by Spearman non-parametric tests with demographics (age, gender, literacy), BMI, type of diabetes, length of the disease, HbA1c value and respect of medication. The analysis of correlations suggests that people with a good adherence to medication have also a better adherence to the specific diabetic diet (carbohydrates counting diet), but not to a healthy, low in animal fats and high in vegetables diet as a whole. The adherence is generally better for type 1 diabetics and also

for people with a longer history of diabetes, probably because of the better learning of the routine required by self-care measures.

Other correlations are obvious (as age and sport) but some are rather surprising, as the correlation between the level of glycemic control, expressed by means of HbA1c, and the hygiene of legs. Presumably, the underlying explanation is that persons with better glycemic control do not neglect even apparent minor details in self-care, as the foot hygiene. (Table 3)

In order to quantify better the influence of the self-care measures on the value of HbA1c, we carried out a logistic regression, after correcting for demographics, drug adherence, type of diabetes, length of the disease. Results showed that the strongest factor related with a better HbA1c value is, as expected, the special diet for diabetics (Exp B= .779, p=.021). Other elements, not less important in the management of the disease, seem to have a rather mediated influence on the dynamics of glycemic control.

In order to bring an order to the above disparate data and explore natural groupings (or clusters) within the diabetics sample, a two-step cluster analysis was chosen, applying the Schwarz`s Bayesian Criterion, taking in account as categorical variable, the adherence to drugs and the diabetes type and as continuous variables, the age, the self-management scores and the values of BP, cholesterol, triglycerides, HbA1c. Two clusters were obtained. No significant differences were observed regarding medicine adherence. But the importance of the self-care management plan seemed highly different. The cluster with the best values of the lipid profile and of the HbA1c (45.8% of the total sample) was formed by patients with a lower age and had the best SCDSA scores in dieting, exercise program, glycemia measurement, foot care.

The patients in the second cluster (54,2% of the total cluster) showed a low adherence to the self-care program, and statistical significantly higher values of the lipid profile and HbA1c. Differences in BP, though not statistically significant, were better in the first cluster, especially the TAS values. Unfortunately, the scores regarding vegetable/fat consumption were unsatisfactory in both clusters, since animal fats were frequently consumed and vegetables/fruits were not eaten in an adequate number of servings. The type of diabetes was not significantly different, but in the first cluster were more type 1 than type 2 patients.

Results are a red flag, their sheer significance being that in the diabetic population some groups cause serious concern regarding self-management, with dreadful consequences on health. Since issues like fruit and vegetable consumption or exercising are important not only for diabetes, but also for other non- communicable diseases, like cardio-vascular ones, frequent companions of diabetes, a better and enhanced training and supervising in this area is compulsive, especially in older patients.

But maybe the most alarming finding of this study is that the glycemic control is generally insufficient, explaining clearly the extent and frequency of complications. Diabetes entails appreciable everyday problems and the risk of complications is large, with impaired quality of life as a consequence. Even life expectancy is shorter than among the rest of the population so the best management of the disease – both by medication, and by self-care measures- is compulsory.

Limitations

Being cross-sectional, our study could not shed light on cause-effect relationships. There is, probably, also an overestimation of the adherence to the medical treatment. The population of Bucharest and Ilfov County, covered by the present study, has a good accessibility and addressability to health services, so maybe the incidence of complications is smaller and the self-monitoring of diabetes is better than in the rest of the Romanian population. The sample was rather small and in future we aim to extend the research on diabetics from other areas of the country, in order to investigate eventual differences and their underlining causes.

Conclusions

The study emphasized again that the diabetic population is heterogeneous and requires a minute follow up, especially regarding the self-management behaviors. If type 1 diabetes seem to cooperate more and better, older, type 2 patients show a lower eagerness of changing lifestyle. Unfortunately, these are also patients with many co-morbidities, implying a high level of medication and handicap and a lower quality of life. So any effort in alleviating this problem would be welcomed. The unhealthy diet and the lack of physical exercise are strong issues, since they trigger not only a negative evolution of diabetes, but also other problems closely linked with the basic disease: high body weight, dislypemia, low cardiac performance, high BP.

On the other hand, an alarming finding is the general poor control of glycemia in the entire sample. The average HbA1c is over what is considered as adequate and, obviously, the number and the extent of complications, high, in spite of the declared good coping with the medication program. A better and closer follow up and monitoring of diabetic patients, a tighter schedule of consultations with the GP and specialist, the onset of a program of support carried out by trained nurses could be answers to serious inadequate behaviors.

A good management of diabetes can decrease the enormous personal and societal costs of complications, patient quality of life and health care resources. Only the contributions of all the levels of the system involved in the management of patients with diabetes (patients, patient families, health care teams, community, etc.) may decrease complications and achieve their socio-economic implication.[30]

Conflict of Interest: None declared

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Table 1: Median values or percents for different specific parametres (type 1 and type 2 diabetics)

Items	**Type 1 N=153**	**Type 2 N=324**	**Total N=477**	**P value**
Present age (years)	37	62	56	0.001
Age onset (years)	25.5	54	48.5	0.001
Length of the disease (years)	10	5	6	0.006
BMI	22	30.1	27.7	0.001
Good adherence to the treatment	80.4%	75.9%	77.4%	ns
Hb1A≥7 (%)	68%	69.4%	68.9%	ns
TAS(mmHg)	120	140	130	0.001
TAD (mmHg)	70	80	80	0.001
Total cholesterol (mg/dL)	198	212	208	ns
HDL (mg/dL)	45	43	45	ns
TGG (mg/dL)	126	169	150	0.001
Complication score	1.77	1.68	1.7	ns

No Renal complications	58.7%	58.5%	58.6%	ns
No eye complications	48.9%	45.7%	46.8%	ns

Table 2: Life style managment habits

During last week	Type 1 diabetes	Type 2 diabetes
Days following the diabetes eating plan (days/week)	7	5
Days with 4-5 portions vegetables/day (days/week)	3	3
Days with animal fats consumption(days/week)	5	4
Exercising at least 30`(days/week)	5	3
Intense Exercising (days/week)	0.6	0.2
Foot check (days/week)	4	3
Shoe check(days/week)	2	0
Smoking (% from the specific diabetic group)	27.5	22.4

Table 3: Significant correlations for SCDSA items

Items	Correlation coefficient (rho)	P value
Diet- BMI	.-167	.038
Diet-diabetes type	.-231	.004
Diet- respect drugs	.369	.001
Diet - HbA1c	.- 261	.001
Moderate sport - diabetes type	-258	.001
Moderate sport - age	-.215	.007
Intense sport - diabetes type	-.271	.001
Intense sport - age	-167	.037
Foot Hygiene - length of disease	-.259	.001
Foot Hygiene- HbA1c	-.243	.001