ORIGINAL ARTICLE

ADHERENCE TO TWO METHODS OF EDUCATION AND METABOLIC CONTROL IN TYPE 2 DIABETICS

Verónica R. Gutiérrez Herrera[1], Hugo Mendieta Zerón[2], Martha R. Mendieta Alcántara[3]

ABSTRACT

BACKGROUND: Education in diabetes optimizes metabolic control, prevents acute and chronic complications, and improves quality of life. Our main objective was to evaluate if a better metabolic control is achieved in diabetic patients undergoing a program of intensive interactive care than in those with traditional care and written information.

METHODS: Patients with type 2 diabetes mellitus (T2DM), aged 20-60 years, education level at least of primary school, serum creatinine ≤ 2.5 mg/dl, self-sufficient and HbA1c ≥ 7.1% were allocated in two groups of education, 1) minimal education (MEG) and 2) full education (FEG). The MEG patients followed predefined diet; FEG patients chose the diet by selecting foods from each group in a list of matches, teaching them to count nutrients, kilocalories (kcal) and percentage of nutrients.

RESULTS: A follow-up of 31 patients in each group was obtained. The proportion of patients who had initial adherence was 13.33% in the MEG group and 9.67% in the FEG group while, at the end of the study, these percentages were of 73.3% and 58.38% respectively. The final HbA1c decreased in both groups, with or without good adherence. The FEG group had a higher decline in the values of cholesterol (p = 0.036) and LDL (p = 0.002) than the MEG group.

CONCLUSION: Education programs in T2DM contribute to a decrease in HbA1c within six months, but an intensive program is more effective in reducing cholesterol and LDL.

KEYWORDS: diabetes mellitus, education, metabolic control.

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INTRODUCTION

Latin America is one of the regions with a highest increase in the incidence of type 2 diabetes mellitus (T2DM) (1), which is the leading cause of death in Mexico (2). Since 1875, Boucharat promoted the education of diabetic patients with the daily urine test and weight loss monitoring as cornerstones in the follow-up of patients with diabetes (3).

As noted by the World Health Organization (WHO), many patients do not understand the medical indications, less than 50% continue their treatment correctly, patients are informed inappropriately about their condition and few are geared to manage and take responsibility of their own treatment (4). As a result, education about self-care strategy is mandatory to all patients.

Training for diabetes self-management is the process of teaching individuals to manage their own conditions, and is considered an important part of clinical management (5). The goals of diabetes education are to optimize metabolic control, prevent acute and chronic complications, and improve the quality of life (6). As a matter of fact, there is knowledge deficiency and skills in diabetes patients up to 50-80% (7), and glycemic control with glycated hemoglobin (HbA1c) < 7.0% is achieved in less than half of people with diabetes (8).

[1]Faculty of Medicine, Autonomous University of the State of Mexico (UAEMex)
[2]Asociación Científica Latina A.C. (ASCILA) and Ciprés Grupo Médico (CGM)
[3]Diabetes Clinic, Regional Hospital “Gral. Ignacio Zaragoza", ISSSTE
Corresponding Author: Martha Ruth Mendieta Alcántara, Email:urania2100@yahoo.com.mx

Educational techniques have evolved and changed into educational interventions that involve the patient in decision-making programs (9). Our main objective was to evaluate whether a better metabolic control is achieved in diabetic patients undergoing a program of intensive interactive care (full education) than in those with traditional care and written information (low education)at the *Clínica de Diabetes, Hospital Regional "Gral. Ignacio Zaragoza", ISSSTE*, Mexico City, Mexico.

MATERIALS AND METHODS

Patients: We invited patients with T2DM, aged 20-60 years, education level of at least primary school, serum creatinine ≤ 2.5 mg/dl, self-sufficient and HbA1c ≥ 7.1%. Those patients not willing to participate were excluded and those missing an appointment during the study were discarded.

Sample: Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 28 subjects per group were necessary to recognize as statistically significant a difference greater than or equal to 1.2 units in glycated hemoglobin. The common standard deviation was assumed to be 1.6. A drop-out rate of 0% was anticipated.

Education strategies: patients were allocated sequentially into two groups of education: 1) minimal education (MEG) and 2) full education (FEG). To reduce selection bias, the medical staff did not do the patient appointment. The MEG patients followed a predefined diet; each of them was given the amount of food rations. FEG patients chose the diet by selecting foods from each group in a list of matches, teaching them to count nutrients, kilocalories (kcal) and percentage of nutrients; in both groups, the aim was to achieve the objectives of the American Diabetes Association (ADA). MEG patients were attended on Mondays and FEG patients on Wednesdays. All patients during the first month were cited each week and then every month until 6 months.

After blood samples, from 9 to 10 am patients had breakfast and filled the directed history (only on the first date), a survey of ingested kcal in the previous 24 hours and a questionnaire about diabetes. Two hours post-breakfast glucose was measured, and the FEG group received education on diet, self-monitoring, exercise, ADA therapeutic objectives and chronic complications through classes and workshops, while the MEG group received written information and explanations only under the patients' request.

The program included explanations about overweight, diet selection, exercise, screening and improved metabolic control, smoking cessation, taking medications and prevention of complications.

A learning assessment was made with the following topics: a) preparation of menus for 3 meals per day, b) identification of food portions based on kcal/day and kcal/carbohydrate, protein and fat (only the education group), c) identification of self-monitoring with emphasis on hypoglycemia and hyperglycemia, d) practice exercise, and e) comparison of drugs and dosage from those indicated.

Anthropometric measures: Height (m) and weight (kg) (Seca, GmbH, Germany) were measured in a standing position. BMI was calculated as weight (kg) divided by height (m) squared. Blood pressure was measured with a mercury sphygmomanometer after 5 min of rest.

Diet: A 24-hour dietary recall was used for this purpose. Diet was categorized within three choices: 1) consumption of 80%-120% of the indicated kcal, 2) less than 80% of the indicated kcal, and 3) greater than 120% of kcal indicated. Diet was classified as dichotomous whether or not it had a balanced proportion of 50%-60% carbohydrates, 10%-20% protein and <30% fat. The calculated kcal was based on the ideal weight minus 200 kcal/day in cases of overweight.

Exercise: Exercise (intensive walking; running or cycling) was reported in days per week of physical activity and min/day. A specific activity was not prescribed due to the heterogeneous work schedule and physical conditions of the patients.

Laboratory: Patients arrived at 7:30 am, after fasting for 12 hours. Venous samples were taken in Vacutainer™ tubes for the determination of glucose, total cholesterol (TC), high-density cholesterol (HDL-C), low-density cholesterol (LDL-C), triglycerides and uric acid (Hitachi 917 ® autoanalizer) and HbA1c. Capillary blood glucose was measured with a Precision® glucose monitor. Serum glucose was measured using the glucose oxidase method and the HbA1c with the turbidimetric inhibition immunoassay (TINIA) method (Roche).

Statistics: Intragroup and intergroup differences between baseline and 6 months' values were analyzed with the Student's t test. Odds Ratio (OR) was used to evaluate the percentage of diet adherence and metabolic control. Pearson correlation was used to determine the relation between metabolic control and exercise and logistic regression analysis for "adherence" was also developed. A p value less than 0.05 was considered significant. All tests were performed with the SPSS v. 15 program.

Ethics: The ethical and research committee of Ciprés Grupo Médico (CGM), Code 2014/01 approved this study. The procedures followed were in accordance with the ethical standards of the General Health Law of Mexico and were subjected to the ethical and moral value judgments of Helsinki.

RESULTS

Patients: A follow-up of 31 patients with minimum education (14 women and 17 men) and 31 patients with full education (11 women and 20 men) was completed. The average age of patients was 51±8 years for the MEG patients and 49±8 for the FEG patients. Both groups showed similar education level (10.4±3.3 years of education in the MEG group and 12.5±3 years in the FEG group) as shown in Table 1.

Table 1: General characteristics of the population (mean ± 1 standard deviation)

	Group			
	Minimum education		**Full education**	
	Mean±SD	**Range**	**Mean±SD**	**Range**
Age (years)	51±8	29-64	49±8	33-66
Women	51.4±8.2	35-64	48±8.4	33-66
Men	49.7±8.4	29-60	48.7-8.2	36-60
Evolution (years)	6.90±4.87	.08-17	7.35±6.8	0.33-25.00
BMI[a]	28.85±5.23	17.8-42.2	28.4±3.7	20.5-36.1
BMI†	28.66±4.84	19.1-41.7	28.9±3.8	20.0-35.8
SBP (mmHg)[a]	122±19	100-180	126±18	100-160
SBP (mmHg)†	120±19	90-170	122±14	100-150
DBP (mmHg)[a]	76±13	60-100	79±15	60-130
DBP (mmHg)†	77±14	50-120	74±8	60-90
C-glu (mg/dl)[a]	218±73	126-400	217±84	76-426
C-glu (mg/dl)†	140±63	6-274	151±55	65-271
2hBG (mg/dl)[a]	265±96	115-450	232±87	61-429
2hBG (mg/dl)†	156±71	61-319	189±56	103-324
V-glu (mg/dl)[a]	226±91	61-530	241±87	98-400
V-glu (mg/dl)†	146±68	77-373	174±94	87-546
HbA1C[a]	11.27±2.46	7.5-18.3	10.8±2.4	7.2-16.7
HbA1C†	7.73±1.59	6.0-12.4	7.7±1.6	5.6-12.1
TC (mg/dl)[a]	219±40	145-334	210±52	142-405
TC (mg/dl)†*	213±40	151-308	186±45	126-303
TG (mg/dl)[a]	265±173	48-908	270±228	87-1160
TG (mg/dl)†	204±114	63-510	219±112	58-412
HDL (mg/dl)[a]	46±13	27-95	43±10	31-69
HDL (mg/dl)†	49±14	34-101	47±11	28-73
LDL (mg/dl)[a]	123±44	13-247	112±35	46-182
LDL (mg/dl)†**	125±29	77-187	94±37	27-170

BMI: Body Mass Index; C-glu: capilar glucose, DBP: diastolic blood pressure; HDL: high-density lipoprotein cholesterol; LDL: high-density lipoprotein cholesterol; SBP: systolic blood pressure; TC: total cholesterol; TG: triglycerides; V-glu: venous glucose, 2hBG: 2 hours post-breakfast glucose, [a]: basal, †: at 6 months. *: $p \leq 0.05$, **: $p \leq 0.01$

Diet

One hundred percent of the patients wrote back the diet report. There was a decrease in the kcal supra-ingestion (> 120% of the indicated Kcal) and infra-ingestion (< 80% of the indicated Kcal), before and after six months (Table 2).

Table 2: Diet adherence*

Kcal intake (% of indicated)	Group			
	Minimum education		**Full education**	
	Basal	After 6 months	Basal	After 6 months
80-120	13	28	21	29
> 120	6	2	4	0
< 80	11	0	6	2

*: Patients who reported diet in minimum education: 30, in full education: 31

The proportion of patients who had initial diet adherence was 13.33% in the MEG group and 9.67% in the FEG group while at the end of the study these percentages were 73.3% and 58.38% respectively. Interestingly, the final HbA1c decreased in both groups, with or without good adherence.

At the beginning of the study, there were 11 patients with a balanced diet and 19 with an unbalanced diet in the MEG group. After six months, the frequency changed to 24 and 6 respectively. In the FEG group, there were 5 patients with a balanced and 26 with an unbalanced diet at the beginning of the study-these numbers changed to 18 and 13 after six months.

For three different situations in diet condition and metabolic control (HbA1c > 7), the highest OR (1.06) was for unbalanced diet and 80%-120% adherence vs other combinations (balance and adherence) in diet (Table 3). Likewise, in the MEG group, the initial value of HbA1c was 10.7% in case of diet adherence and 12.8% without adherence, and after six months, the percentages changed to 7.59% and 7.55% respectively. In the FEG group, the values changed from 11.84% to 7.4% and 10.51% to 7.28% for the same conditions.

Table 3: ORs for HgA1c > 7

Comparison	Diet	OR	95% CI
1	Unbalanced and 80-120% adherence Others	1.06	0.36 to 3.16
2	Unbalanced and < 80% adherence Others	0.57	0.03 to 9.72
3	Balanced and 80-120% adherence Unbalanced and 80-120% adherence	0.56	0.18 to 1.75

We also noted that Pearson test in females (n = 32) showed a positive significant correlation between adherence and carbohydrate intake (p = 0.002). On the contrary, the correlation was negative to proteins when the analysis was made only in males (n = 17) (p = 0.026); in this subgroup, the diet portion of lipid was also significant. We also found that Pearson test showed a positive correlation for adherence and “kcalei”.

By logistic regression analysis with the dependent variable “adherence”, the only independent variable with statistically significant difference was “kcalei” (percentage of indicated caloric intake).

Exercise: In the specific topic of exercise, the MEG group began the study with nine patients practising it, and after the observation period, 23 patients were motivated to practise physical movement. In the FEG group, these numbers were 10 and 31 respectively. We ended the study with an average exercise of 2.89 days per week in the MEG group and 4.54 in the FEG group.

Self-control and knowledge evaluation: At the beginning of the study, none of the patients reported self-control capabilities and after the intervention program; the percentages reached were of 89.51 in the MEG group and 68.92 in the FEG group.

The general diabetes knowledge examination test gave a result of 1.79 in the MEG group at the beginning and 8.16 in the end, while the FEG group had values of 1.77 and 8.51 (all in scale from 0 to 10 points).

Laboratory: The change in value ranges in metabolic variables are presented in Table 4. The FEG group had a higher decline in the values of cholesterol (p = 0.036) and LDL (p = 0.002) than the MEG group.

Table 4: Variables by rank

	Minimum education (patients)		**Full education (patients)**	
	Initial	**After 6 months**	**Initial**	**After 6 months**
SBP (mmHg)				
≤ 120	20	20	17	23
121-140	6	10	8	4
> 140	5	1	6	4
DBP (mmHg)				
≤ 80	25	28	25	28
81-90	2	3	1	2
> 90	4	0	5	1
HbA1c (%)				
≤ 7	0	9	0	13
7.1-8	2	9	5	10
> 8	29	13	26	8
TC (mg/dl)				
≤ 200	10	14	16	20
201-250	13	15	11	9
> 250	8	2	4	2
TG (mg/dl)				
≤ 150	8	10	13	16
151-200	4	7	2	3
> 200	19	14	16	12
HDL-C (mg/dl)				
≤ 45	17	17	20	18
45.1-60	12	9	8	11
> 60	2	5	3	2

DBP: diastolic blood pressure; HDL-C: high-density lipoprotein cholesterol; SBP: systolic blood pressure; TC: total cholesterol; TG: triglycerides

In relation to renal function, in the MEG group, two patients began with creatinine higher than 1.25 mg/dl, and three finished with values higher than this with one requiring dialysis. In this group, seven patients began with uric acid higher than 7 mg/dl while ten patients ended the study with this value or higher. In the FEG group, one patient began with creatinine higher than 1.25 mg/dl, and three patients finished the study with values above this. Paradoxically, at the beginning of the intervention, none of the patients had uric acid above 7 mg/dl, but there were five at the end.

Metabolically (HbA1C), the change shows that in the MEG group, the percentage of controlled patients was 0% in the beginning and 20% reached clinical targets after six months. In the FEG group, the variation increased from 0% to 18.18%.

In relation to the total cholesterol, in the MEG group, the percentage of controlled patients at baseline was only 32.2% (N = 31) and 32% (N = 25) at the end, while in the FEG group, the percentage increased from 51.6% (N = 31) to 59.0% (N = 22). The triglycerides showed a good trend control from 25.8% (N = 31) to 40% (N = 25) in the first group and diminished from 45.1% (N = 31) to 27.2% (N = 22) in the second one. The HDL-C greater than 60 was kept in two cases in the first group, and in three cases, in the second group.

According to the Student t test, there were statistically significant differences ($p \leq 0.001$) between initial and last values of the next variables: HgA1c, fasting serum glucose, fasting capillary, 2 hours post breakfast capillary, total cholesterol, triglycerides, HDL, and LDL this among all patients without grouping. Intergroup T test (MEG vs FEG) showed a difference for total cholesterol ($p = 0.036$) and LDL ($p = 0.002$) at the sixth month.

The Wilcoxon test for the MEG group evidenced significant differences between the initial recruiting and after six months' follow-up values for BMI ($p = 0.042$), serum fasting glucose ($p = 0.002$), 2 hours post breakfast capillary ($p = 0.002$), fasting capillary ($p = 0.006$), HbA1C and

HDL (p = 0.021). The same test in the FEG group demonstrated significant differences in serum fasting glucose (p = 0.001), fasting capillary (p = 0.007), HbA1C, total cholesterol (p = 0.020), HDL (p = 0.036) and LDL (p = 0.002).

An inverse relationship was observed between minutes of exercise and HbA1c, which was demonstrated by linear regression and Pearson correlation. It is interesting to note that our patients decreased their level of HgA1c at a greater rate in the MEG group than the FEG group.

Drugs: From the MEG group, four patients were taking pravastatin and two were taking fibrates at the beginning; one was able to avoid the drug. At the end, this group registered six patients with pravastatin and three with fibrates. In the FEG group, three patients were taking pravastatin, one of them later suspended this drug but at the end, another one had to be prescribed with this treatment.

It is notable that only two patients in the MEG group did not require a change in the therapeutic scheme, contrasting with the other 60.

DISCUSSION

T2DM can be effectively controlled with an intervention model based on group care, which emphasizes the interactive educational techniques stimulating patient cooperation. Nevertheless, educational programs are very demanding for the healthcare staff, requiring a lot of time, specific training and communication skills. Points to consider for an ideal self-management intervention are feasibility, practicality in a wide variety of cases, motivation, and effectiveness to maintain important physiological results in the long term, improving the quality life (10).

Norris et al. (11) conducted a systematic review of self-care training in T2DM, concluding that the intervention effects on lipids, physical activity, weight and blood pressure were variable. In this respect, some studies that have measured changes in diabetes show improvement when adding an education program (12-14), but long-lasting studies are disappointing. For example, Wing et al. (15) focused on adjustments in diet and physical activity in conjunction with self-monitoring of serum glucose, identified a failure in showing glycemic improvement after one year. By comparison, we can see that virtually all patients evolved to a better condition, but six months is insufficient to achieve the ADA goals (HbA1c: 7%; preprandial plasma glucose: 70–130 mg/dl; postprandial plasma glucose: less than 180 mg/dl). With the advancement of science and technology, a step forward would be enough to harness the Internet to allow patients to self-monitor and keep updated through the website of the health institutions, as has already been experienced (16).

Most studies evaluating dietary changes have shown positive results in self-reports, including improvement in the intake of carbohydrates and lipids and a decrease in total kcal (17-18). Educational interventions in diabetes with a short follow-up up to 6 months tended to show greater efficacy (19-20). In this survey, education, either intensive or usual, seems to achieve normalization in Kcal ingestion.

In this study, in the MEG group, the number of patients practising exercise increased 2.5 times more, while in the FEG this increase was of 3.1. To some extent, this is consistent with Wood (21) who noted an increase in physical activity after 4 months of intervention, Glasgow et al. (22) that found an increase in the number of minutes of activity three months after intensive education and Wierenga (23) who found an increase in physical activity after 5 sessions at the 4 month.

Group-based training for self-management strategies in people with T2DM is effective in improving fasting blood glucose levels, HbA1C and diabetes knowledge and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication (24). Maintaining an average HbA1C decrease might lead to a decrease in the lifetime to develop microalbuminuria, neuropathy and retinopathy (25). The decrease in blood pressure and lipid levels help reduce cardiovascular risk (26). As published by several authors (27-28), our results also show changes in some variables after implementing an educational program.

Drug therapy is indicated if the response to altered diet and exercise is inadequate (29). This study provides an important insight as to the possibility of achieving adequate metabolic control in diabetic patients managed with glyburide, metformin and insulin in health institutions with limited resources.

A proactive management plan should include patient-centered goals for controlling hypertension, lipid levels, and glycaemia (30). Several aspects of our group care model deserve special attention. First, it was effective in promoting appropriate health behaviors and metabolic improvement leading to a decline in BMI. Second, this technique stabilized HbA1c and increased HDL. Moreover, the difference in HbA1c remained significant after adjustment for BMI. Similarly, the multivariate analysis showed that HbA1c improvement did not depend on age and duration of diabetes.

Now, it is perfectly demonstrated that intensive control prevents complications of diabetes, but it is difficult to keep a group with the same strategy for a long time. From our data, we recommend that each diabetes clinic evaluate the time at which losses exceed 20% of a total cohort in follow up to design strategies to keep patients in close monitoring. This should set the parameters for a national strategy in order to keep patients on surveillance. In our population, we can say, in general, that fewer kcal in proteins or fats is related to a better adherence.

Despite intensive intervention, lifestyle changes and drug treatment, there is a progressive worse metabolic control in patients with T2DM (31). One reason for the poor results in individuals with diabetes is the lack of eligibility in the intervention program. Motivation is a key to acquire knowledge, and keep adherence in a hard life regimen. Our results reinforce the need for and the benefits of incorporating education in selected patients. Effective programs for self-care of diabetes should not be complex, need be individualized and reinforced over time (32).

While further work is required to define the effectiveness of interventions aimed at self-care in T2DM on sustained glycemic control in detail, two limitations of our study are the small number of patients and the non-randomization process to offer the education method. It is worth noting the positive benefits in a short time (six months) and with a minimum medical staff. These results might be bolstered with a better patient selection based on education level.

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