

## Assessment of a Key Message in Newly Diagnosed Type 2 Diabetes Mellitus Patients Considering Their Educational Program

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### Abstract

**Background:** It is well known that therapeutic nutrition education provided to patients with new diagnosed type 2 diabetes mellitus is crucial in terms of subsequent adherence to a dedicated multi-factorial treatment. The patient could be empowered to act on insulin dose and/or on other aspects (calorie intake, therapeutically efforts and sleep schedule etc.) regarding the achievement of the final therapeutic targets.

**Objective:** The aim of this retrospective study was to determine the impact of the message perceived by patients with new diagnosed type 2 diabetes mellitus on the means used in achieving metabolic control at 3 months of treatment after an initial educational program.

**Method:** We performed a retrospective, case-control study of 143 patients with new diagnosed type 2 diabetes mellitus patients admitted to general hospital wards to investigate the relationship between remaining messages after attending our educational program with all methods to achieve adequate metabolic control. It was hypothesized that message have a great impact considering all methods to achieve this targets and are associated with a greater impact of dose insulin.

**Result:** At the moment of evaluation we find that the dose of insulin is significantly different between the two lots:  $0.43 \pm 0.02$  UI/Kgc vs.  $0.13 \pm 0.01$  UI/Kgc,  $p < 0.05$ ; and the level of physical therapeutic effort is also significantly different  $2.12 \pm 0.35$  MET/day vs.  $3.51 \pm 0.32$  MET/day,  $p < 0.05$ . At the same time weight loss, as well as HbA1c levels that the groups reached, have statistical significance ( $p < 0.05$ ).

**Conclusion:** We could say at the final of our study that the main message of our program is associated with a lower dose of insulin used for treatment of type 2 diabetes mellitus patients.

**Keywords:** Dose of insulin; Type 2 diabetes mellitus; Message for education

### Introduction

It is well known that therapeutic nutrition education provided to patients with newly diagnosed type 2 diabetes mellitus is crucial in terms of subsequent adherence to a dedicated multi-factorial treatment. The patient could be empowered to act on insulin dose and/or on other aspects (calorie intake, therapeutically efforts, sleep schedule etc.) regarding the achievement of the final therapeutic targets [1].

Teaching self-management of diabetes to patients in hospitals is a challenging task considering that the patient is present here because an acute illness. Patients are ill, under increased stress related to their hospitalization and diagnosis. This is not an environment conducive to learning [2]. A single specialist consult is not enough to empower the patient with all the skills regarding his future chronic status. Ideally, people with diabetes should be taught at a time and place appropriate for learning: as an outpatient in a recognized program of diabetes education. For the hospitalized patient, diabetes “survival skills” education is generally a feasible approach to provide sufficient information and training to enable safe care at home [1].

Educational programs are a significant demand on health care providers, requiring large blocks of time (generally uncompensated), specific training, teaching and communication skills, a supportive attitude, and a readiness to listen and negotiate. Concomitant, this program is perceived by patients as a dedicated space and time especially when this educational program is provided for small groups (3-6 persons) [3].

Because type 2 diabetic patients are often both insulin-resistant

and having hypertriglyceridemia, a number of groups have examined the effects of regular exercise on glycaemic control and risk factors for atherosclerotic vascular disease in these patients. The idea that excessive concentrations of insulin might contribute to the development of atherosclerosis appeared in the mid-1960s, and the evidence was first reviewed in an article published in 1969. Since then, clinical and experimental data have continued to accumulate, most of it supporting the hypothesis, although some of the details have had to be modified [4]. Although the evidence that regular exercise, adequate diet and treatment can improve glucose tolerance, diminish insulin resistance and improve coronary risk factors in some patients with type 2 diabetes is reasonably compelling, the therapeutic efficacy of exercise in such patients may be questioned.

Therefore, effective education requires training in its delivery and a lot of time to implement it. Furthermore, even if diabetes education were accepted by health care providers and covered by health insurers, many societies would not have sufficient qualified diabetes educators to

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meet the demand. Even if a complete education program is provided, the treatment of diabetes could have a great impact on weight control [5]. This lack of educational resources is critical everywhere, especially in developing countries which the World Health Organization estimates to be among the regions with a great increase in occurrence of diabetes in Europe. Even now, 80% of the diabetes disability-adjusted life-years lost worldwide occur in developing countries [6-8].

## Material and Methods

### Objective

The aim of this retrospective study was to determine the impact of the message perceived by patients with newly diagnosed type 2 diabetes mellitus on the means used in achieving metabolic control at 3 months of treatment after an initial educational program.

### Design

In two departments of "Carol Davila" Military Hospital (Endocrinology Department and Diabetes Department), a retrospective study regarding the final message received from different medical doctors considering this program was conducted.

The metabolic control was defined considering ADA recommendation: for general population, a HbA1c lower than 7%. A unique meeting was held after 3 months of the program attended by patients who achieve the metabolic control (HbA1c <7%) and only these patients were admitted in this retrospective study.

Initial message, which was randomly chosen by the patient, was:

1. To maintain basal blood glucose targets using any dose of insulin (no matter how big is the dose) that the patient touched in his presented algorithm. The patient also used other therapeutic methods considered available (diet, therapeutic exercise, metformin) already presented by the physician.
2. To try to maintain a basal blood glucose targets using a minimum possible insulin dose - with the use of other therapeutic methods considered available (diet, therapeutic exercise, metformin) already presented by the physician.

After the patient understand this message, we made two matched groups. Two groups with comparable biological parameters have been selected - weight, sex, triglycerides, baseline glycated haemoglobin.

We performed a retrospective, case-control study of patients with newly diagnosed type 2 diabetes mellitus admitted to general hospital wards to investigate the relationship between remaining messages after attending our educational program with all methods to achieve adequate metabolic control. It was hypothesized that message might have a great impact considering all methods to achieve this targets and could be associated with a greater impact of dose insulin. For example, some authors provided arguments supporting the hypothesis that hyperinsulinemia is the underlying cause some complications of type 2 diabetes mellitus, there is a possibility for improving metabolic health by suppressing hyperinsulinism, and the role of environmental agents in this process [8,9].

Furthermore, we predicted that the association of insulin dose with metabolic control could vary by type of transmitted message.

### Subjects and methods

In previous programs with Healthy Nutrition Foundation and "N Paulescu" National Institute of Diabetes, we developed a simple

educational program targeted to newly diagnosed type 2 diabetic patients, consisting in 5 minutes-3 meetings, after the patient was discharged. The published methods and data guiding the development of this intervention are shortly presented next lines: the program consisted in a letter for using home and for next meetings (which contained questions as a first "cue" for patients to think about targets). This is presented as a patient information leaflet for a short program during 15 minutes with the diabetes care provider or educator (divided in 3 meetings). Patients who were not able to attend the all 3 meetings before starting this study received written information with the same content, but they were not accepted in this study [10].

All patients signed the inform consent. The Helsinki Declaration was respected.

We addressed a total of nine determinants of health-seeking behaviour:

1. Compliance meals,
2. Calculating carbohydrates,
3. Therapeutic targets,
4. Basal insulin dosing and adherence to medication,
5. Sleep schedule compliance,
6. Therapeutic Exercise,
7. Daily Stress Management,
8. Infections,
9. Other health events (hypoglycaemia).

In the same time, a biological status was evaluated to be compared with initial one, from the first visit, and the patient agreed to be compared with these results.

Splitting the 2 lots for this study was performed according to the answer of single question mentioned above; data were then collected and processed statistically. Patients with newly discovered type 2 diabetes were selected, with basal insulin as indication, after 3 months of treatment, with a HbA1c lower than first visit.

Two primary techniques are available for health providers and patients to assess the effectiveness of the management plan on glycaemic control: patient self-monitoring of blood glucose (SMBG) and HbA1c. All patients have SMBG during this period.

The HbA1c test is subject to certain limitations. Conditions that affect erythrocyte turnover (hemolysis, blood loss) and hemoglobin variants must be considered, particularly when the HbA1c result does not correlate with the patient's clinical situation. In addition, HbA1c does not provide a measure of glycemic variability or hypoglycemia. For all patients who have insulin in treatment, prone to glycemic variability, we initially recommended to have an adequate glycemic control (at least twice a day). Finally, we combined the results of SMBG and the HbA1c. The HbA1c may also serve as a check on the accuracy of the patient's meter (or the patient's reported SMBG). In the same time, HbA1c was a parameter to be studied, because we tried to have comparable lots at the beginning of the study, considering this parameter.

### Statistical analysis

On the assumption of a non-respected educational program recommendation rate of 20% per period studied, we estimated that

70 patients were required in each of the two groups to achieve 80% power to detect a significant difference with a two-sided  $\alpha$  error of 0.05. All tests used a P value < 0.05. The same p was considered to indicate statistical significance. All data are represented as mean  $\pm$  SD. A statistical package was used to compute some descriptive statistics.

## Results

The study was realised during January 2013-March 2014. We realised two matched lots considering initial evaluation, at the start of treatment. The results are available using the discharge letter. All patients attended the educational program. The initial evaluation is presented in Table 1 (3 months ago).

The current assessment was made considering that their evaluation is done during normal consultations. They were asked to complete a questionnaire on weight reached, exercise level measured using estimating scales and some date considering the current insulin dose they use to achieve a therapeutic target blood sugar levels that are established, after 3 months of treatment. Meanwhile biochemical profile was collected. The results are presented in Table 2.

At the moment of evaluation, we found that the dose of insulin is significantly different between the two lots:  $0.43 \pm 0.02$  UI/Kgc vs.  $0.13 \pm 0.01$  UI/Kgc,  $p < 0.05$ ; and the level of physical therapeutic effort is also significantly different  $2.12 \pm 0.35$  MET/day vs.  $3.51 \pm 0.32$  MET/day,  $p < 0.05$ . At the same time weight loss, as well as HbA1c levels that the groups reached, have statistical significance ( $p < 0.05$ ). Could we say at least theoretically that the main message of our program is the key of these findings? Using ANOVA tests we have same significance of our results.

Characteristics	Lot 1	Lot 2	P value (t student)
Number of patients	72	71	
Age	54.72 $\pm$ 8.36	55.79 $\pm$ 10.51	$p > 0.05$
Men/Women	34/38	35/36	
Metformin	1760.4 $\pm$ 324.3 mg	1850 $\pm$ 295.9 mg	$p > 0.05$
Insulin (initial dose recommendation)	0.515 $\pm$ 0.09 UI/Kgc	0.49 $\pm$ 0.07 UI/Kgc	$p > 0.05$
<b>Biochimic profile</b>			
Glycemia (mg/dl)	225.58 $\pm$ 21.28	231.28 $\pm$ 58.62	$p > 0.05$
HbA1c (%)	10.54 $\pm$ 1.29%	10.13 $\pm$ 1.81%	$p > 0.05$
Total Cholesterol (mg/dl)	224.9 $\pm$ 34.13	214.05 $\pm$ 35.49	$p > 0.05$
Creatin (mg/dl)	0.85 $\pm$ 0.15	0.81 $\pm$ 0.29	$p > 0.05$

Table 1: Comparable studied lots (initial values).

Characteristics	Lot 1	Lot 2	P value (t student)
Number of patients	72	71	
Age	54.72 $\pm$ 8.36	55.79 $\pm$ 10.51	$p > 0.05$
Men/Women	34/38	35/36	
Metformin	1760.4 $\pm$ 324.3 mg	1850 $\pm$ 295.9 mg	$p > 0.05$
Insulin (actual dose recommendation)	0.43 $\pm$ 0.02 UI/Kgc	0.13 $\pm$ 0.01 UI/Kgc	$p < 0.05$
<b>Biochimic profile</b>			
Glycemia (mg/dl)	125.58 $\pm$ 21.28	91.28 $\pm$ 8.62	$p < 0.05$
HbA1c (%)	7.14 $\pm$ 1.29%	6.13 $\pm$ 0.81%	$p < 0.05$
Total Cholesterol (mg/dl)	124.9 $\pm$ 34.13	114.05 $\pm$ 35.49	$p > 0.05$
Creatin (mg/dl)	0.84 $\pm$ 0.45	0.81 $\pm$ 0.21	$p > 0.05$
Level of therapeutic activity	2.12 $\pm$ 0.35 MET/day	3.51 $\pm$ 0.32 MET/day	$p < 0.05$
Weight loss	0.24 $\pm$ 0.12kg	2.12 $\pm$ 0.21kg	$p < 0.05$

Table 2: After three month of treatment - the actual results.

## Conclusions and Discussions

Using our intervention program we have good results considering clinical and biological tests after 3 months of application. There are significant differences between lots and the same comprehensive educational program addressed to new type 2 diabetes mellitus patients have a better impact considering level of therapeutic activity if the main remaining message is formulated in this proposed "strategic" way.

In the same time we could observe that there is a negative correlation between insulin dose and therapeutically effort (-0.36, for CI 95%). It is well known that this correlation exists; this study shows us again that the main message of an educational program could have a great impact considering the final results of this project.

That regular exercise decreases plasma insulin levels and enhances insulin action in humans was first suggested by studies in trained athletes. Samuel et al. [11] presented studies where two groups of normal weight, middle-aged subjects (one group consisted of individuals who were highly trained cross-country skiers and the other group consisted of age- and weight-matched non-athletes) used the effort as a tool for enhance insulin action. Anyway, the hypothesis that regular exercise enhances insulin action was confirmed [12].

The International Diabetes Federation estimates that 285 million people around the world have diabetes. This total is expected to rise to 438 million within 20 years. Each year a further 7 million people develop diabetes, and in the same time the cost for each patient considering insulin are increasing. The strategic approach to manage with chronic diseases like diabetes mellitus, coronary heart disease, asthma, cancer or other common illness is called disease management (DM). DM has evolved from managed care in the 1970's USA and is defined as "a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant" and refers to the processes and people concerned with improving or maintaining health in large populations [6].

The general idea is to ease the disease path, rather than cure the disease. DM programs (DMP) are no replacement for medical treatment but they are supportive actions. There are lots of supportive actions with a quantifiable impact regarding the disease evolution. A simple main message supports the physician or practitioner/patient relationship and could have a great impact to self-management education (therapeutically efforts, self-monitoring, compliance etc.). Taking home a final message as a part of a complex educational program is a necessity and the patient should be more informed about his options considering the disease control, treatment and medication [13]. In the same time a final message could have a great impact in view of long term evolution and progression of disease, but more studies are need to be done.

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