A Model Educational Program for People With Type 2 Diabetes

A cooperative Latin American implementation study (PEDNID-LA)

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OBJECTIVE — To implement an educational program in 10 Latin American countries and to evaluate its effect on the clinical, biochemical, and therapeutic aspects as well as the economic cost of diabetes.

RESEARCH DESIGN AND METHODS — Educators from each participating country were previously trained to implement the educational model. The patient population included 446 individuals with type 2 diabetes; all patients were <65 years of age, did not require insulin for metabolic control, did not have severe complications of diabetes or life-limiting illnesses, and had not previously participated in diabetes education courses. Clinical and therapeutic data and the cost of their pharmacological treatment were collected 6 months before participation in the educational program (~6 months), on entry into the program (time 0), and at 4, 8, and 12 months after initiation of the program.

RESULTS — All parameters measured had improved significantly (*P < 0.001) by 1 year: fasting blood glucose (mean ± SD) 10.6 ± 3.5 vs. 8.7 ± 3.0 mmol/l, HbA₁c, 9.0 ± 2.0 vs. 7.8 ± 1.6%; body weight 84.6 ± 14.7 vs. 81.2 ± 15.2 kg; systolic blood pressure 149.6 ± 33.6 vs. 142.9 ± 18.8 mmHg; total cholesterol 6.1 ± 1.1 vs. 5.4 ± 1.0 mmol/l; and triglycerides 2.7 ± 1.8 vs. 2.1 ± 1.2 mmol/l. At 12 months, the decrease in pharacotherapy required for control of diabetes, hypertension, and hyperlipidemia represented a 62% decrease in the annual cost of treatment ($107,939.99 vs. $41,106.30 [U.S.]). After deducting the additional cost of glucosuria monitoring ($30,604), there was still a 34% annual savings.

CONCLUSIONS — The beneficial results of this educational model, implemented in 10 Latin American countries, reinforce the value of patient education as an essential part of diabetes care. They also suggest that an educational approach promoting healthy lifestyle habits and patient empowerment is an effective strategy with the potential to decrease the development of complications related to diabetes as well as the socioeconomic costs of the disease.

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Diabetes presents a substantial socioeconomic and quality-of-life burden (1), mainly as a consequence of its chronic complications. Despite unequivocal data that chronic complications can be prevented or delayed by improved glycemic control and treatment of concomitant cardiovascular risk factors (2,3), a large proportion of individuals with diabetes develop these complications.

One reason for the poor outcomes in individuals with diabetes is the lack of participation in the treatment of the disease. This participation is a key success factor in the treatment of diabetes that demands motivation, knowledge, and compliance to a difficult and complex lifetime regimen.

As early as 1875, Bouchardat (4) was promoting patient education, daily urine testing, and weight reduction as cornerstones of therapy in type 2 diabetes; education is widely accepted as integral to diabetes therapy within the diabetes community (5–7). However, in many countries, only a minority of patients receive diabetes education (8). Limited knowledge of diabetes is frequent among individuals with diabetes (9). This deficiency can be partly ascribed to the low priority of patient education among practitioners, payers, public health opinion leaders, and decision-makers.

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 (10). Therefore, effective education requires training in its delivery (11). Furthermore, even if diabetes education were to be accepted by health care providers and covered by health insurers, many societies would not have sufficient qualified diabetes educators to meet the demand.

This lack of educational resources will become critical in Latin America, which the World Health Organization estimates to be among the regions with the greatest increase in occurrence of diabetes (12). Even now, 80% of the diabetes disability-adjusted life-years lost worldwide occur in developing countries (13).

This problem was addressed by diabetologists from several Latin American countries during a recent conference sponsored by the Latin American Diabetes Association (ALAD). They discussed the feasibility of finding a common and flexible educational program suitable for implementation in the countries of the re-
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RESEARCH DESIGN AND METHODS

Structured educational model
The program was based on that of Davidson (18). It was designed and adapted to local conditions by a multidisciplinary group of health care professionals (16,19). The course was presented to no more than 10 ambulatory patients in a group setting that allowed interaction between the educator and participants. The primary goal of the course was to improve health behavior.

The course included four weekly teaching units (90–120 min each) and a reinforcement session at 6 months. Family members and spouses were encouraged to attend.

The first unit. The first teaching unit acquainted patients with the interactive group method, provided general concepts about type 2 diabetes and self-monitoring, and emphasized active patient participation in treatment. Patients were introduced and asked to talk about their diabetes. They were then instructed about the physiological changes in serum glucose levels, the symptoms of hypoglycemia and hyperglycemia, and the renal threshold for glucose. As a practicum, the patients were shown how to perform and record glucosuria self-monitoring. The urine glucose test was chosen as the most practical means of training patients with type 2 diabetes about biochemical self-control; normoglycemia was not the goal of the program. Additionally, the cost of self-monitoring of blood glucose was unlikely to be borne by the health care systems studied.

At the end of the first unit, the patients were asked to follow a low-calorie diet (600 calories per day) on alternate days until the next weekly session and to discontinue use of oral hypoglycemic agents (OHAs) to prevent hypoglycemia. They were also asked to monitor glucosuria twice daily (2 h after the main meal) and to record the findings in a logbook, along with daily body weight. The goal was to learn how food intake affects glucose and glucosuria.

The second unit. During the second teaching unit, the patients discussed the evolution of their disease, the effect of obesity on insulin sensitivity, and the advantages of weight reduction. Patients were taught to assign foods to the categories of “recommended,” “neutral,” and “to be avoided,” using the Plate Model, a simple alternative to the traditional exchange method (20). The dinner plate shows the portion of the plate that would be covered by 100 calories of various foods. Benefits include enhancement of the connection between dietary theory and practice, promotion of memory retention and understanding through visual messages, and experience of a positive approach to nutrition counseling (20). Each patient designed an individual meal plan (1,000 cal/day) and was urged to follow it. The educator reemphasized the importance of glucosuria self-monitoring to observe the influence of diet on metabolic control.

At the beginning of the third and fourth teaching sessions, the patients had an opportunity to discuss their experiences with the meal plan, body weight, and glucosuria self-monitoring initiated during the first and second units.

The third unit. The main topics discussed during the third teaching unit were foot care and regular physical activity. The educator also performed foot examinations.

The fourth unit. During the fourth teaching unit, the basic rules for “sick days” (intercurrent episodes of acute disease) were explained and examinations and laboratory tests necessary for good diabetes care were defined.

Educational materials. Educational materials used during the program included the following: 1) a set of 25 colored flip charts to illustrate the most important aspects of each unit; 2) teaching files for the educator as a structured guideline on how to perform each session; 3) a set of 50 photographs of different foodstuffs representing 100 cal each; 4) questionnaire cards for distribution to participants as a standardized procedure for verifying knowledge acquired in previous sessions, correcting misinterpretations, and reinforcing the main concepts; 5) individual logbooks for recording all the self-monitored data (glucosuria and body weight); 6) patient booklets including the main contents and other aspects of the program; and 7) questionnaires for evaluation and documentation of the patients’ diabetes-related knowledge both before and after the program. The same Spanish-language materials were used in all countries except Brazil, where the materials were translated into Portuguese. Additionally, some photographs of foodstuffs characteristic of a particular country were added to the materials used in that region.

Training of participating teachers
The program was implemented simultaneously in Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Mexico, Paraguay, and Uruguay (see Appendix). Before the program, all educators participated in an intensive 10-person 2-day training seminar that included basic pedagogic principles, handling of small interactive educational groups, using the education material, and achieving the active participation of patients instead of passive listening.

Patient selection and study design
The study was coordinated by a scientific committee centered in La Plata, Argentina (CENEXA), that was responsible for training the educators from the 10 participating countries in diagnostic testing (use of the same reagents, kits, and laboratory procedures), interventions, data registries, and analysis of results to ensure standardization.

Inclusion criteria for participants were type 2 diabetes, overweight or obesity (BMI >27), and neither ketonuria nor use of insulin. Exclusion criteria were ages >65 years, advanced chronic complications of diabetes (retinopathy, nephropathy with creatinine >2 mg/dl, or neuropathy), other severe life-limiting illnesses, inability or unwillingness to participate in the diabetes education program and/or the diagnostic procedures of the project, and participation in previous structured diabetes education courses. Individuals who fulfilled the inclusion criteria and agreed to participate were included in the study after providing informed consent. This study conforms with principles stated in the Declaration of Helsinki.
In each PEDNID-LA group, eligible volunteers were selected randomly from the patients who periodically came to each clinic for control of diabetes. A total of 658 patients were enrolled initially, but records for the preceding year were incomplete for 212 patients; therefore, the final study group included 446 patients. Statistical analysis showed no significant differences between the clinical and biochemical data recorded for the 446 patients who were studied and the 212 patients who were excluded (data not shown).

After the completion of the program, we evaluated clinical data, metabolic control and cardiovascular risk factors (obesity/overweight, hypertension [systolic and diastolic], and hyperlipidemia diagnosed according to the European Association for the Study of Diabetes [EASD] criteria) (21), drug intake (used to control diabetes and other risk factors), and cost of pharmacological treatment. For this purpose, data were collected 6 months before participation in the program (−6 months), on entry into the program (time 0), and 4, 8, and 12 months after initiation of the program (see RESULTS). After completion of the program, data from each patient were compared with data from the same patient at time 0.

Clinical data included medical history, duration of diabetes, body weight, BMI, drug intake, annual hospitalization rate, major illness, cardiovascular symptoms, and smoking habits. Blood pressure was measured at every visit, and 12-lead resting electrocardiography was performed annually in all participants. Data were also recorded concerning blood pressure and the daily intake of OHAs and lipid-lowering agents.

Blood samples were collected at each visit in the morning after 12 h of fasting and after considering all other metabolic and physical conditions of the patients as stated in the PEDNID-LA protocol for HbA$_1c$ (normal range 4.3–5.8%) (Tina Quanti HbA$_1c$ II; Roche Diagnostics, Mannheim, Germany), glucose (glucose-oxidase method; Roche Diagnostics), total cholesterol, and triglycerides (enzymatic method; Roche Diagnostics). To measure each of these biochemical parameters, the participating laboratories strictly followed the instructions provided for each method by the manufacturer of the reagent used. In the particular case of cholesterol analysis, the standardization procedure followed the guidelines of the National Education Program from the U.S.

The data were recorded using a common data form and were sent to CENEXA for compilation and analyses. To estimate the changes in the cost of drugs taken by the participants before and after the courses, medications were classified as OHAs, antihypertensive drugs, or cholesterol-lowering drugs; glibenclamide, enalapril, and simvastatin were selected as representative of each of these classes, respectively. The annual cost of medication was estimated by multiplying the number of patients using each drug the percentage of patients taking each medication before and after the program) by the average daily intake and the average price of the drugs on the Argentine market. Similar reasoning was applied to estimate the annual cost of the urine-glucose strips used by all of the participants. In this case, we assumed that none of the patients were using strips at time 0 and all patients were using them at 12 months.

Statistical analysis

The primary outcome was defined as a difference between HbA$_1c$ levels measured at the beginning and the end of the study. The power calculation was based on a previous study with similar patient characteristics (16). The formula used (22) assumed the following: $\alpha$-error = 0.05; potency (1–$\beta$) = 0.80; decreased to be detected = 0.5; standard deviation of the expected change = 1.5.

The data were analyzed at the CENEXA facilities using the Database and Statistical Program for Public Health Epidemiology 6 (version 6.02; Centers for Disease Control and Prevention and World Health Organization, 1994) and the CSS/Statistica software (Statsoft 1994). Differences between clinical and biochemical parameters at different time periods were obtained by repeated-measures analysis of variance (Student-Neuman-Keuls post hoc test), taking into account the variation in the number of cases recorded during the study, whereas differences between proportions in an unadjusted univariate analysis were tested for statistical significance by the $\chi^2$ test.

RESULTS — The characteristics of the 446 patients who met all of the protocol requirements and whose previous clinical records were complete are shown in Table 1. The average duration of the disease was 8 years. Of the total participants, 92% were either overweight or obese ($n$ = 410), 45% had systolic hypertension ($n$ = 200), 44% had diastolic hypertension ($n$ = 197), 62% had high serum cholesterol.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Values</th>
<th>Degree of control*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>54.6 ± 10.1</td>
<td>—</td>
</tr>
<tr>
<td>Duration of diabetes since diagnosis (years)</td>
<td>8.0 ± 13</td>
<td>—</td>
</tr>
<tr>
<td>Drug intake†</td>
<td>OHAs</td>
<td>76</td>
</tr>
<tr>
<td></td>
<td>Antihypertensive drugs</td>
<td>49</td>
</tr>
<tr>
<td></td>
<td>Cholesterol-lowering agents</td>
<td>10</td>
</tr>
<tr>
<td>BMI (kg/m$^2$)‡</td>
<td>31.5 ± 5.6</td>
<td>24/25</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)†</td>
<td>137 ± 20.5</td>
<td>140</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)†</td>
<td>84.9 ± 11.8</td>
<td>90</td>
</tr>
<tr>
<td>Fasting blood glucose (mmol/l)</td>
<td>10.2 ± 3.3</td>
<td>&lt;6</td>
</tr>
<tr>
<td>HbA$_1c$, (%)†</td>
<td>8.9 ± 2</td>
<td>&lt;6.5</td>
</tr>
<tr>
<td>Cholesterol (mmol/l)†</td>
<td>5.5 ± 1.1</td>
<td>&lt;5.2</td>
</tr>
<tr>
<td>Triglycerides (mmol/l)†</td>
<td>2.1 ± 1.4</td>
<td>&lt;1.7</td>
</tr>
</tbody>
</table>

Data are % and means ± SD. *Figures correspond to “good” degree of control (21). †Total patient population = 446; 92% were obese ($n$ = 410), 45% had systolic hypertension ($n$ = 200), 44% had diastolic hypertension ($n$ = 196), 62% had high serum cholesterol ($n$ = 277), 53% had increased triglyceride levels ($n$ = 236), and 72% percent had HbA$_1c$, >6.5% ($n$ = 321). ‡The percentage is applied to the number of people with the corresponding pathology, i.e., diabetes, hypertension, and high cholesterol levels, respectively.
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Changes in the population sample after attending the education courses

<table>
<thead>
<tr>
<th>Time period</th>
<th>Fasting blood glucose (mmol/l)</th>
<th>Body weight (kg)</th>
<th>Systolic blood pressure (mmHg)</th>
<th>Diastolic blood pressure (mmHg)</th>
<th>Triglycerides (mmol/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>10.6 ± 3.5 (446)</td>
<td>84.6 ± 14.7 (46)</td>
<td>149.6 ± 33.6 (200)</td>
<td>91.9 ± 11.5 (179)</td>
<td>2.7 ± 1.8 (277)</td>
</tr>
<tr>
<td>1 month</td>
<td>9.0 ± 3.0 (464)</td>
<td>81.6 ± 14.9 (48)</td>
<td>146.6 ± 33.6 (200)</td>
<td>95.4 ± 7.9 (179)</td>
<td>1.9 ± 1.1 (327)</td>
</tr>
<tr>
<td>3 months</td>
<td>8.8 ± 1.0 (464)</td>
<td>82.2 ± 14.9 (48)</td>
<td>138.7 ± 15.9 (179)</td>
<td>92.8 ± 7.9 (179)</td>
<td>1.9 ± 1.1 (327)</td>
</tr>
<tr>
<td>6 months</td>
<td>8.9 ± 1.0 (464)</td>
<td>82.2 ± 14.9 (48)</td>
<td>138.7 ± 15.9 (179)</td>
<td>92.8 ± 7.9 (179)</td>
<td>1.9 ± 1.1 (327)</td>
</tr>
<tr>
<td>9 months</td>
<td>8.8 ± 1.0 (464)</td>
<td>82.2 ± 14.9 (48)</td>
<td>138.7 ± 15.9 (179)</td>
<td>92.8 ± 7.9 (179)</td>
<td>1.9 ± 1.1 (327)</td>
</tr>
<tr>
<td>12 months</td>
<td>8.8 ± 1.0 (464)</td>
<td>82.2 ± 14.9 (48)</td>
<td>138.7 ± 15.9 (179)</td>
<td>92.8 ± 7.9 (179)</td>
<td>1.9 ± 1.1 (327)</td>
</tr>
</tbody>
</table>

Data are means ± SD of the number of cases at each time period. Fasting blood glucose (mmol/l) was measured by repeated-measures analysis of variance (Student–Neuman–Keuls post hoc test), taking into account the variation in the number of cases.

CONCLUSIONS — Conflicting results have been obtained regarding the effectiveness of dietary advice on body weight and metabolic control. Hadden et al. (23) reported a cohort of patients who lost an average of 9 kg during the first 6 months and maintained the weight loss for 6 years; 87% of the patients were still being treated with diet alone after 1 year and 71% were being treated with diet alone.
Our results demonstrate that education of individuals with type 2 diabetes can be cost-effective and beneficial (7,8,16,17,26–28,30). Even after discounting the cost of self-monitoring urine glucose levels, the decrease in drug intake represents a mean savings of 34% in pharmacotherapy. This decrease, along with the corresponding reduction in the lifetime risk for developing chronic complications, could result in a diminution of the socioeconomic burden and an improvement in quality of life for individuals with diabetes.

The dropout rate was significantly lower than the 50% previously observed in a similar population (1,16). We were unable to identify a priori patient characteristics predicting those who would or would not successfully complete the follow-up period. Identification of such characteristics would be useful to identify people who would benefit from a different educational approach and is worthy of further study.

Our results suggest that patient empowerment is an effective approach to developing educational interventions for addressing the psychosocial aspects of living with diabetes (31). Although no single educational strategy has been demonstrated to have a clear advantage (32), group-oriented learning improves relationships between patients and health care professionals, allows peer interaction, and instills a sense of competition (33). Moreover, our results further support the concept that an educational program provided through small group classes meets a variety of needs (e.g., cost-effectiveness and convenience for patients, educators, and physicians) while promoting adaptive changes in behavior for improved food selection, increased levels of physical activity, and improved control of glycemia and risk factors associated with type 2 diabetes (34).

The beneficial long-term clinical, metabolic, and pharmacological effects of the implementation of the current educational model have been reported in individuals with type 2 diabetes from industrialized (8,14,15) and developing countries (16,17) with gross differences in socioeconomic and cultural conditions. Because of the number of participating centers, the size of the sample, and the methodology used for patient selection, the population recruited in each center may not necessarily represent the general population of each participating country. However, the data do provide a reasonable example of how social environment and lifestyle habits vary in the Latin American region. Despite this potential limitation, the present study supports the flexibility of the model and the possibility of extending its implementation to other countries with different sociocultural settings.

Our results reinforce the need for and the benefits of incorporating patient education, either using this or other alternative models, as a regular and essential part of diabetes care and as an effective means of reducing chronic complications of diabetes. Furthermore, allocating resources to such educational programs seems to be a wise allocation of scarce funds in the countries studied. The data presented support the idea that such an approach has the potential to decrease the socioeconomic costs of diabetes and to improve the quality of life of individuals with diabetes.

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APPENDIX

The PEDNID-LA administrative organization was in charge of the Executive Committee and the General Coordinator, in addition to the International Committee for Technical Cooperation. The PEDNID-LA Executive Committee includes Antonio Chacra (Brazil), Gloria López (Chile), and Eric Mora Morales (Costa Rica). The general coordinator is Juan José Gagliardino and Associates.
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