A Randomized Trial Comparing Intensive and Passive Education in Patients With Diabetes Mellitus

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Background: Patient education is a cornerstone of treatment in diabetes mellitus, but there is not unanimity of opinion as to how it should be delivered.

Objective: To determine whether a single, intensive group educational program would improve glycosylated hemoglobin (HbA1c) levels when compared with passive education.

Methods: A total of 106 patients with HbA1c levels greater than 8.5% were randomized to either an intensive (n=50) or a passive education (n=56) group. The intensive education group received 3.5 days of a structured curriculum involving a physician, nurse, nutritionist, pharmacist, exercise physiologist, and a social worker. The passive education group received material sent by mail every 3 months providing basic information on topics related to diabetes management. Patients continued care with their diabetes care provider during the study period. Levels of HbA1c were measured at baseline and 3, 6, and 12 months after randomization. A matched control group of individuals who declined participation also had HbA1c levels measured at baseline and 12 months.

Results: Mean ± SD HbA1c levels fell significantly (P < .001) from baseline (9.9% ± 1.3%) in both the intensive (~2.0%) and passive (~1.9%) education groups at 12 months, and there was no difference between the groups at any evaluation time. Both groups had significantly greater decline (P < .03) in HbA1c levels than a matched control group (~1.2%) with similar baseline HbA1c levels that did not receive education.

Conclusions: Patients with elevated HbA1c levels who were receptive to education had substantial improvement in HbA1c levels after receiving an educational intervention. In this population, intensive or passive methods of delivering patient education seemed to have similar effect on improving glycemic control.

Diabetes mellitus (DM) is a chronic disease that requires ongoing care tailored to the needs of the patient. Patient education is considered a cornerstone of treatment in DM. Education alone may not be sufficient to improve patient outcomes, but it forms the framework on which medications, nutrition, and other lifestyle modifications are built. Approximately 50% to 80% of people diagnosed as having diabetes lack significant knowledge and skills to manage the condition effectively. One of the goals of Healthy People 2010 is to increase to 60% the proportion of individuals with diabetes who receive formal diabetes education. While there is no unanimity of opinion as to how we should deliver education, there is consensus on the necessary content for an educational program.

Traditionally, diabetes education has been aimed at increasing patient adherence with physician-defined therapeutic goals and treatment strategies. One reason this approach may not consistently result in good outcomes is lack of participation by individuals in their own treatment. Active participation by patients demands motivation, knowledge, and adherence to an often difficult and complex lifetime regimen.

The present study compared the effectiveness of a single intensive group educational program (designed to improve knowledge and encourage active participation by patients in their diabetes management) with a passive education program. Our goal was to gain insight into the relationship between the type of educational intervention and its effect on glycemic control.

RESULTS

The baseline characteristics of the 106 randomized participants are as follows: The mean age was 60 ± 3 years; 99% were men; and mean body mass index (calculated as weight in kilograms divided by height in

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PATIENTS AND METHODS

The study was conducted at the Veterans Affairs Boston Healthcare System, Boston, Mass, and was reviewed and approved by the institutional review board. Informed written consent was obtained from each participant prior to entry into the study. Hospital laboratory data were screened on a monthly basis for potential study participants by identifying individuals with an elevated glycosylated hemoglobin (HbA1c) level (>8.5%). A total of 912 individuals were identified over a 6-month recruitment period and were sent a letter describing the study and soliciting their participation. Follow-up telephone calls were placed to all of these potential participants at least 2 weeks after sending the recruitment letter. Telephone contact was made with 380 individuals: 211 declined participation; 63 were ineligible; and 106 participated (Figure 1). Patients were deemed eligible if they met the following criteria: HbA1c level greater than 8.5% (measured within 30 days of randomization); age 18 years or older; able to exercise; available to participate (if randomized to the intensive education program); and able to understand written and spoken English. Participants were excluded if they had significant eye disease limiting visual acuity; urine protein level greater than 2 g/d; coronary artery disease symptoms; and/or lower extremity amputation that limited exercise capacity. We compared 2 educational programs: an intensive education group and a passive education group.

INTENSIVE EDUCATION GROUP

Participants randomized to the intensive group received 3.5 days of a structured curriculum through lectures, group discussions, and supervised exercise. The sessions were conducted in groups of 4 to 6 participants and contained all the core elements recommended by the American Diabetes Association for diabetes education curricula. Participants had an initial evaluation performed by a certified diabetes educator to determine their current knowledge base and individual needs and goals. Two meals and snacks were provided on each day of their participation as a means of reinforcing the nutritional instruction. Professionals actively involved in the program included a physician, nurse, nutritionist, pharmacist, exercise physiologist, and a social worker. A certified diabetes educator was charged with overseeing each participant throughout the course of the educational program. After completing the intensive educational program, participants were returned to their usual care. Of the 50 individuals randomized to receive intensive education, all but 1 participated in and completed the program. Data from the individual who did not participate were included in the analyses.

PASSIVE EDUCATION GROUP

Participants in the passive group received educational materials mailed to their home every 3 months. The educational materials included booklets (15–45 pages) containing the following themes: general diabetes management, nutrition, coronary artery disease, and foot care. All patients received their usual medical care in addition to the educational materials. Fifty-six individuals were randomized to receive passive education. Participants in both groups were asked to return 3, 6, and 12 months after randomization for measurement of HbA1c levels.

CONTROL GROUP

From the group of 211 individuals with HbA1c levels greater than 8.5% who were contacted but declined participation, we identified individuals who had HbA1c levels measured again at a mean±SD follow-up of 12±3 months from an initial screening level. We matched 36 persons by age, sex, and baseline HbA1c level to those in the passive education group.

HbA1c ASSAY

Glycosylated hemoglobin levels were measured in the hospital laboratory. High-performance liquid chromatography was used to separate the hemoglobin components and to measure the 6 fractions of hemoglobin, including the HbA1c component.

STATISTICAL ANALYSES

Data are expressed as means±SDs unless indicated otherwise. All analyses compared subjects according to their status at randomization and were conducted in an “intent-to-treat” manner, with the last value carried forward for missing data. Variables not normally distributed underwent appropriate transformation. Comparisons within groups were performed using analysis of variance with repeated measures. Comparison among groups was performed by 2-way analysis of variance, using Bonferroni correction when appropriate. A 2-tailed probability level lower than .05 was considered statistically significant.

During the course of the study we tracked medication changes in randomized participants. At the end of 12 months, participants in the intensive education group were more likely to be undergoing oral combination therapy (more than 1 oral agent) and less likely to be undergoing monotherapy with an oral agent (Figure 3) than participants in the passive group. The percentage of patients receiving combination therapy of insulin with an oral agent was similar to the percentage receiving insulin alone.

To address the question of whether the similar decrease in HbA1c in both groups was an effect of intervention, a result of regression to the mean, or a result of
ongoing care, we pooled the intervention groups and compared them with a matched control group of individuals who declined participation in the study. There was no significant difference between the baseline HbA1c levels of the intervention and control groups: 9.9% ± 1.3% and 9.8% ± 1.2%, respectively. At 12 months, these levels had decreased to 8.0% ± 1.4% and 8.6% ± 1.8%, respectively. There was a significantly greater decline in HbA1c level in the combined intervention groups than in the control group (P < .03).

**COMMENT**

Our study demonstrates that an educational intervention in patients with diabetes mellitus has a significant effect on HbA1c level, but the manner in which it is delivered is not important. The decrease in HbA1c level of approximately 2.0% after 1 year in both intervention groups is significant and similar to that obtained in the Diabetes Control and Complications Trial, which also showed that a 2% decrease in HbA1c level reduces the risk of future complications by 70%. Maintaining this mean decrease in HbA1c level would represent a significantly reduced lifetime risk for microalbuminuria, retinopathy, and neuropathy.

We were surprised to find that there was no significant difference in the metabolic control achieved in the single intensive education and the passive education treatment groups. It is likely that the participants who enrolled in the study were highly motivated and, regardless of group assignment, prepared to make a change in their diabetes control. For this reason we compared both groups with individuals drawn from the same pool of patients who declined participation. These individuals also had a decline in HbA1c level, but it was significantly less than that of the intervention groups. Thus, the modest intervention given to the passive education group was sufficient to achieve a significant reduction in HbA1c level.

There is evidence to suggest that changes in attitude and motivation are needed to achieve metabolic control in patients with diabetes, and integrating educational interventions with intensive insulin treatment is important in achieving metabolic control. Contrary to this evidence, the present randomized controlled study showed that passive education integrated with ongoing care achieved glycemic control similar to that achieved by intensive education. Our results suggest that offering diabetes education to patients who are interested in receiving it may be cost-effective and cost beneficial, based on improvement in glycemic control. This decrease in HbA1c level with the added benefit of corresponding reduction of lifetime risk for developing chronic complications could also result in improvement in quality of life for individuals with diabetes.

The overall effect of education on glycemic control in patients with diabetes is mixed. Length of follow-up after the educational intervention may affect the findings of a study—studies with less than 6 months follow-up tend to demonstrate greater effectiveness than studies with longer follow-up. Few studies with longer follow-up have shown significant effects on glycemic control. Two studies demonstrated improved glycemic control and 10 others showed no significant effects despite regular patient contact. In some studies the method of education delivery affected the improvement in glycemic control. Compared with didactic interventions, collaborative interventions produced favorable results, particularly if the interventions were repetitive and ongoing. Indeed, part of the effectiveness of the passive education offered to our patients may have come from the repetitive nature of the mailings that patients received. Nevertheless, our study suggests that patient education in diabetes need not require face-to-face contact to have significant effects, particularly when targeted to a motivated group of patients.

Our results reinforce the need for and benefits of incorporating educational interventions into the management of patients with diabetes. Furthermore, passive educational methods had a similar effect on HbA1c levels when compared with intensive education. This suggests that any educational method that provides instruction in the core content areas, particularly when
delivered to patients who are interested and receiving ongoing care, can be an effective means for reducing HbA1c levels.

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