Management of Obese Patients With Diabetes Mellitus: Comparison of Advice Education With Group Management

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The purpose of our study was to compare the effect on diabetes control of group management with the advice-educational technique traditionally used in managing obese outpatients with poorly controlled non-insulin-dependent diabetes mellitus (NIDDM). Forty-one patients were randomly assigned to these two treatment programs, and 32 patients completed the 6-mo study. Initially, patients were seen for 1-h sessions at 1- and 2-wk intervals and later at 1-mo intervals. Patients were asked to do home blood glucose monitoring, decrease caloric intake, increase exercise, and if they were taking insulin, to adjust the dose to attain approximate euglycemia and to stabilize food and exercise patterns. The combined groups reduced mean ± SD glycohemoglobin from 10.9 ± 3.1 to $9.4 \pm 2.4\%$ ($P < .05$). Internal Health Locus of Control Scale was negatively and significantly correlated with initial and subsequent glycohemoglobin values (the more internal, the lower the glycohemoglobin). At the end of the study the patients in the group management program had significantly lower blood glucose levels than those given advice and education, but no significant differences in glycohemoglobin values or percentage overweight were observed. One patient had a normal initial glycohemoglobin, and only 4 patients had values in the normal range of 4–6.8% at the end of the study. Better management programs need to be developed for treating obese outpatients with NIDDM. DIABETES CARE 1986; 9:490–96.

There is substantial evidence in animals that many of the chronic complications of diabetes mellitus can be averted, delayed, or reduced by prolonged normalization of serum glucose. Similar evidence in humans is suggestive but not conclusive.[1] In addition to recognizing the probable advantages of good control, we now have the knowledge, devices, and drugs that should allow almost all obese patients with non-insulin-dependent diabetes mellitus (NIDDM) to approximate euglycemia. However, in our clinic, euglycemia is uncommonly attained by these patients. The failure to achieve this goal is not a peculiarity of our clinic.[2–4]

The usual management techniques used in our clinic are based on advice and education. In our study, obese outpatients with NIDDM were randomly assigned to an advice-education program or to a group management program in which patient interaction was used to try to improve diabetic control. The effectiveness of both programs was examined by determination of body weight, serum glucose, and glycohemoglobin levels before, during, and after the study.

METHODS

Patients. The charts of 300 patients attending the Tucson Veterans Administration Medical Center Diabetes Clinic were reviewed to find obese patients with NIDDM who met the following criteria: *1*) men with diabetes mellitus and less than satisfactory control, defined as fasting serum glucose usually >140 mg/dl and 1-h postprandial values usually >180 mg/dl; *2*) infrequent hypoglycemic reactions (<1/mo), absent or rare ketonuria that was never more than moderate when the patient was not fasting, and no history of diabetic ketoacidosis; *3*) body weight >15% above the mean value for height according to the 1959 Metropolitan Life Insurance Tables for medium-frame subjects[5]; *4*) no history of current alcohol abuse or severe personality disorder; *5*) no current use of glucocorticoids.

The 110 patients who met the selection criteria were contacted to determine their interest in attending an intensive diabetic treatment program. Forty-one of these patients were recruited for the study. Before the study began, all subjects had been informed in their routine clinic visits about the

adverse effects of hyperglycemia and hypoglycemia and urged repeatedly to decrease body weight to normal and increase physical activities to try to restore their glucose tolerance to normal. They were told that restoration of their serum glucose to normal would probably make them feel better and would decrease their likelihood of developing the chronic complications of diabetes. Rendell,[6] in a study of 102 patients with diabetes mellitus starting after age 25 yr, managed to reduce body weight to normal in 38 of the patients. Fourteen of these 38 patients had normal glucose tolerance tests at the end of the treatment program. In our study, only if advice to reduce body weight and to increase exercise failed to reduce serum glucose to normal were patients advised to take insulin. Oral hypoglycemic agents were not used. All patients were urged to try to maintain normal blood glucose levels and all had been taught to do home blood glucose monitoring before the study began.

Tests. At baseline and on every return visit, the patients had a serum glucose determined with a glucose oxidase method (Astra-8, Beckman; Fullerton, CA) and measurement of body weight. At baseline, after 3 mo and at the end of the study, the patients had glycohemoglobin determined with affinity chromatography and colorimetry (Glycoglobin Kit, Endocrine Sciences, Tarzana, CA). At the beginning and end of the study, a test on knowledge about diabetes mellitus and a questionnaire on locus of control were administered. Demographic data were collected at the time of the baseline visit.

The knowledge test was a 20-item multiple-choice questionnaire constructed to assess the subject's understanding of the cause, signs, and treatment of NIDDM associated with obesity. The α-coefficient for internal consistency for this instrument was 0.79 at baseline and 0.71 at the final visit. Two questions from the questionnaire asked what causes diabetes and what is large blood vessel damage (atherosclerosis).

The Internal Health Locus of Control questionnaire[7] is designed to measure the extent of personal control individuals believe they have over their own state of health. Evidence suggests that people who have an internal health locus of control (believe their health is the result of their own doing) are more likely to practice health-related behaviors.[8] The standardized α-coefficient for this five-item subscale was 0.77 at baseline and 0.72 at the final visit. Two statements taken from the Internal Health Locus of Control Scale[7] are: "The main thing which affects my health is what I myself do"; and "If I take the right action, I can stay well."

Treatments. The patients were prestratified into insulin-treated and non-insulin-treated groups and then randomly assigned to either an advice-education control program or to an experimental group management program. The advice-education control group was further separated into two groups according to whether therapy included the administration of insulin. There were 12 subjects in the insulin control group and 4 subjects in the non-insulin-treated control group. The advice-education control group format was designed to minimize subject interaction by having a nurse and a dietitian give lectures on the disease and its management. Lecture content included the rationale for and the behaviors consis-

tent with attaining euglycemia. Each patient also met once with the dietitian to prepare an individual diet plan. Diet management emphasized the restriction of calories as a means of weight reduction and the use of high-fiber foods with a low glycemic index for normalization of blood sugar.[9] The glycemic index is an expression of the change in blood glucose after eating the particular food containing 50 g of carbohydrate compared to the change in blood glucose after a similar meal of sucrose.[10] Subjects were instructed on the benefits of exercise, weight loss, and glucose reduction.[9,11] Correct insulin administration was reviewed with emphasis on the subject's performance of home blood glucose monitoring and guidelines for adjusting insulin dosage.

The experimental patients were subdivided into three smaller groups of less than eight members; two groups of insulin-treated patients and one group of non-insulin-treated patients. These groups met separately with a clinical psychologist experienced in small group management. The psychologist was briefly trained in the management of obese patients with NIDDM by observing a nurse clinician handling these patients in our diabetes clinic for 4 h and by reading current medical articles on this topic. In addition, an endocrinologist served as a consultant on call for the psychologist during and between experimental group sessions and attended two of the experimental group sessions to make sure that the psychologist gave well-informed answers to patients' questions. Experimental group subjects were encouraged to interact and assess their own and their peers' progress toward managing their diabetes by sharing ideas, advice, and support with one another. The rationale of the group-management approach was based on social-psychological research that has shown that changing food habits can be facilitated by a group-decision process.[12] The group process was used to assist the patients in changing their dietary and exercise habits. Weekly serum glucose levels of each member as well as results of the two glycohemoglobin tests were posted on a blackboard and discussed at each group meeting. In a small-group problem-solving format, patients shared ideas and provided mutual support for dietary change and increased exercise levels. Therapeutic group management represents a form of social interaction and support based on reference-group theory. The theory proposes that attitudes and behaviors may be shaped by membership and that an individual's evaluation of how well he or she is doing results from appraisals of others and by comparing his or her situation with that of others. Dissatisfaction with one's own results in comparison with the results of others may lead to striving for achievement.[13] Reference-group support has been used effectively in producing behavior changes in smokers and in hypertensive patients.[14,15]

Both groups met for 10 1-h sessions scheduled weekly during the 1st mo, biweekly the 2nd mo, and monthly for the remaining four meetings. The second and ninth meetings were audiotaped and analyzed to see if the experimental treatment had been satisfactorily implemented, i.e., to see if interactions were usually from subject to subject or subject to leader and not leader to subjects.

The effects of the two treatments separately and combined

TABLE 1
Comparison of control and experimental patients before study

Variable	Patients recruited		Patients evaluated	
	Control (N = 21)	Experimental (N = 20)	Control (N = 16)	Experimental (N = 16)
Demographic				
Age (yr)	60.7 ± 6.9	62.4 ± 6.1	60.7 ± 6.4	62.4 ± 5.5
Duration (yr)	12.9 ± 8.9	12.3 ± 13.6	13.6 ± 9.6	10.1 ± 12.9
Insulin dose (U/day)	59.9 ± 40.6	53.7 ± 29.3	65.3 ± 44.2	44.8 ± 17.5
	(N = 15)	(N = 14)	(N = 12)	(N = 12)
Married (%)	85.7	80.0	93.8	81.3
Education > high school (%)	38.1	35.0	37.5	31.3
Employed (%)	33.3	25.0	31.3	25.0
Physiologic				
Overweight (%)	40.9 ± 16.3	36.4 ± 21.8	44.3 ± 21.0	36.3 ± 21.0
Glycohemoglobin (%)	11.5 ± 3.5	11.0 ± 2.6	11.3 ± 3.5	10.4 ± 2.6
Glycohemoglobin (number normal)	1	0	1	0
Serum glucose (mg/dl)	279 ± 120	238 ± 119	260 ± 117	221 ± 123
Questionnaires				
Internal Health Locus of Control (0–6)	4.3 ± 1.2	4.0 ± 1.3	4.0 ± 1.1	4.5 ± 1.0
Knowledge test (0–20)	14.2 ± 3.6	11.3 ± 3.9*	14.2 ± 3.6	11.3 ± 3.8*

Values are means ± SD. *Means different at $P = .02$. All other means were not significantly different.

were analyzed in terms of subject characteristics associated with metabolic control as measured by serum glucose and glycohemoglobin values.

Statistics. The SPSSX statistical package was used for analysis of the results.[16]

RESULTS

The characteristics of the 41 patients assigned to the two treatment programs are compared in Table 1. The average patient was >60 yr old with a history of diabetes for more than 12 yr. Seventy-one percent of the patients were taking insulin (mean dose 57 U/day). Most were married, unemployed, and educated at or below the high-school level. As a group they were very obese (mean 138.7% of the Metropolitan Life Insurance Table values[5]), had a mean serum glucose of 259 mg/dl, and had a glycohemoglobin of 11.3% (normal range 4–6.8%).

Glycohemoglobin test. The interassay coefficient of variation in our laboratory for a glycohemoglobin sample with a mean value of 6.1% was 2% (N = 9).

Dropouts. Initially there were 21 subjects in the control group and 20 in the experimental group. Nine subjects (22%) subsequently dropped out. Illness, death, or leaving the state accounted for five of the dropouts, whereas four subjects offered no explanations. Subject attrition from the experimental and control groups and from insulin- and non-insulin-treated groups was similar. Analysis of demographic data and physiological outcomes revealed that the subjects who discontinued the diabetic program had significantly higher mean blood glucose levels (325 mg/dl) than the subjects who re-

mained in the program (240 mg/dl). The initial glycohemoglobin values demonstrated differences similar to that of serum glucose, i.e., dropouts had 12.7% and those who stayed had 10.9%. However, this difference was not statistically significant. No differences between the dropouts and those completing the study were observed with regard to age, marital status, employment, educational level, disease duration, knowledge of diabetes, or internal health locus of control. The dropouts attended a mean of 2.8 meetings (out of 10) compared to 8.7 for those who stayed.

Analysis of advice-education versus group management. The 32 subjects who ultimately completed the 6-mo study were equally divided between the experimental and control groups. The effect of random assignment in achieving equivalent pretest groups was assessed through χ^2-analyses and t tests of mean differences. The results indicate no significant differences between the groups with respect to the variables listed in Table 1 except for the results of the knowledge test. The mean number of correct responses on the diabetes knowledge test at baseline was significantly higher for the advice-education control than for the experimental group management patients.

Analysis of the duration and direction of patient-staff interactions recorded at two meetings showed that patient-initiated interactions were approximately three times longer for the experimental group subjects than for the controls at the second meeting ($P < .001$) and twice as long at the ninth meeting ($P < .01$) (Fig. 1). A similar comparison between the smaller (N = 4) and the larger (N = 12) advice-education control groups indicated no significant differences due to group size. The results indicate that the group management
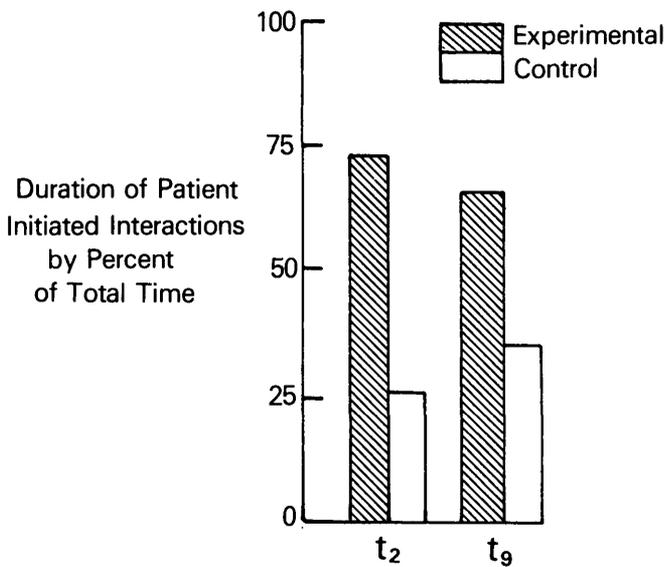
FIG. 1. Duration of patient-initiated interactions plotted as percent of total interaction time when examined at 2nd (t_2) and 9th (t_9) meetings. Totals are <100% because of uncertainty regarding origin of certain interactions.

format was successfully implemented for the experimental group. There was no significant difference between the groups regarding the number of meetings attended.

The physiologic outcomes for the two groups are shown in Fig. 2. The mean percent overweight for both groups remained high and was not significantly different between the groups. There was a decline in mean serum glucose levels in both groups in the first 3 mo. In the last 3 mo there was a gradual but continued decline in mean serum glucose values for the experimental group, whereas the education group's mean increased and was significantly greater than the mean for the experimental group on the final visit (243 vs. 161 mg/dl, respectively; $P < .05$). There was a decline in glycohemoglobin levels in the first 3 mo that was similar to the initial decline in serum glucose levels. However, little change occurred in glycohemoglobin concentration during the final 3 mo of the program. One patient assigned to the control group had a normal glycohemoglobin value initially, and four (one control, three experimental) had values in the normal range at the end of the study. At no time were the glycohemoglobin values for the groups significantly different from one another. The poststudy scores of the diabetes knowledge tests for the experimental and advice-education groups were significantly different (12.5 vs. 15.4, respectively); however, as noted earlier, the groups were not equivalent in this respect. Both groups experienced a similar, small gain in knowledge during the 6-mo program (scores increased 1.2 for both the control and experimental groups). An analysis of variance by relative percent change indicated that the gains in knowledge within each group were significant ($P < .05$), but between-group differences were insignificant.

Analysis of both treatment groups combined. In the absence of meaningful differences between the groups, it seemed appropriate to combine the data from the two treatment programs to identify factors that might be associated with differences in metabolic control within the total sample.

The mean percent overweight throughout the 6-mo study showed little change (40.3–39.3%) (Fig. 3). The mean serum glucose concentration decreased from its initial value of 240 mg/dl by 22.1% after 2 mo but subsequently rose to a final value of 202 mg/dl. The first six meetings were held at 1- or 2-wk intervals, while after 2 mo the meetings were monthly. The mean glycohemoglobin concentration decreased from its initial value of 10.9% to its value at the 3-mo visit and then remained stable. The final mean glycohemoglobin value was 13.8% less than the original value ($P < .05$), but it remained far above the upper limit of normal (9.4 vs. 6.8%).

There were no significant correlations of initial glycohemoblobin levels with age, duration of disease, age at onset, insulin dose, marital status, level of education, or the results of the knowledge test. However, the more internal the locus of control, the lower the initial glycohemoglobin ($r = .32$,
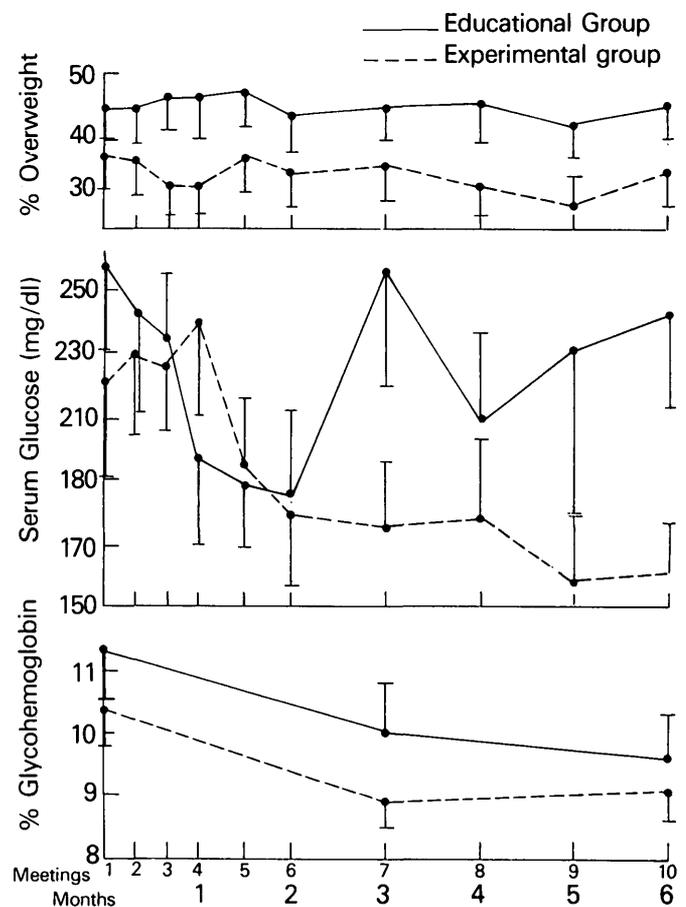

FIG. 2. Mean percent overweight, serum glucose, and percent glycohemoglobin of each treatment group plotted as functions of time and number of visits. Bars indicate SEM.
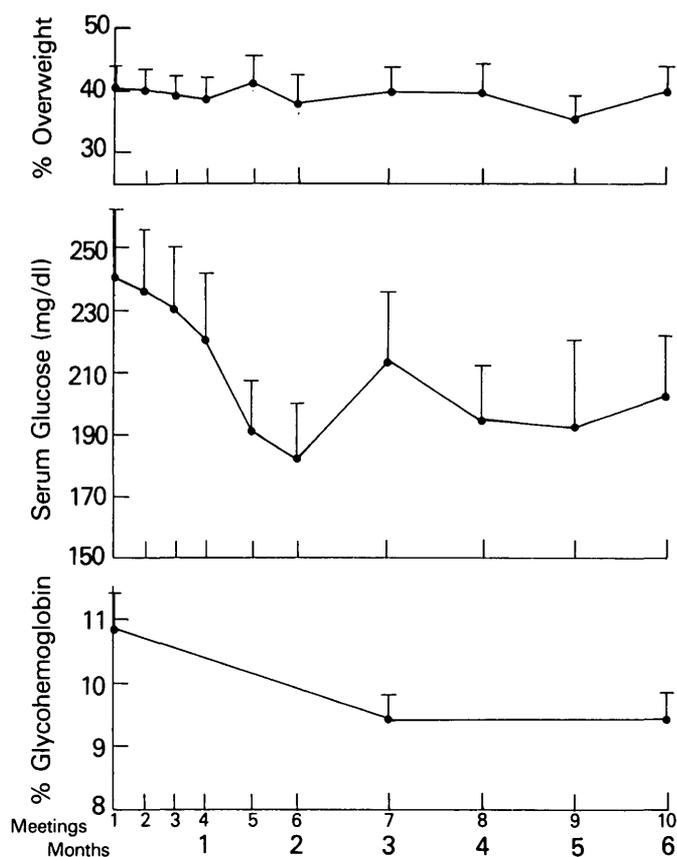
FIG. 3. Mean percent overweight, blood glucose, and percent glycohemoglobin for all patients who completed study plotted as functions of time and number of visits. Bars indicate SEM.

$P = .04$). The magnitude of the correlation involving health locus of control increased with subsequent glycohemoglobin measurements ($r = .50$, $P = .03$ at 3 mo and $r = .57$, $P = .01$ at 6 mo).

Another method of ascertaining subject characteristics that might be associated with a reduction in glycohemoglobin was examination of the correlations of the available baseline subject data with absolute and relative percent change in glycohemoglobin during the program. Relative percent change in glycohemoglobin was computed by subtracting the poststudy value from the prestudy value and dividing by the prestudy value minus the mean normal glycohemoglobin level

TABLE 2
Pearson product-moment correlations with change in glycohemoglobin

Variables	Glycohemoglobin	
	Absolute % change	Relative % change
Internal Health Locus of Control	0.23 ($P = .107$)	0.22 ($P = .111$)
Number of meetings attended	0.39 ($P = .013$)	0.37 ($P = .020$)

$N = 32$.

(5.4%). Thus, relative percent change takes into account reduction relative to the proximity of the prestudy value to the normal or desired level. The Pearson correlation coefficients indicated that there was a tendency for internal health locus of control and number of meetings attended to be correlated with the percent change in glycohemoglobin (Table 2). The more internal the locus of control and the more meetings attended, the greater the reduction in glycohemoglobin.

DISCUSSION

Management based on advice and education that is used in traditional clinic systems is not a very effective method for all patients with NIDDM. The patients in this study were selected because they were failures in terms of the therapeutic goals of the system through which they received care. Specifically, they were hyperglycemic and obese and, even if they were taking insulin, they did not take enough to approximate euglycemia even after being advised to increase their dose of insulin.

The patients who were assigned to the program of additional advice and education had only a 15% decline in their elevated glycohemoglobin and only 1 out of 16 had a normal glycohemoglobin at the end of the study.

The experimental design of the group management program was successfully implemented as indicated by the significantly longer duration of patient-initiated interactions in these groups. At the end of the study, the patients in the group management program had mean levels of glycohemoglobin that were not significantly different from the mean of the advice-education group. However, mean levels of the serum glucose values determined at the time of the meetings were significantly lower in the group management than in the advice-education patients. Whereas the advice-education patients were told individually about the results of their serum glucose and glycohemoglobin determinations, the laboratory results for the experimental group management patients were displayed on a blackboard for all to see. Discussion of each other's laboratory results and progress was a major activity at the meetings of the experimental groups. The subjects may have responded to peer pressure by better controlling their serum glucose levels at the time of the meetings. Serum glucose was a more frequently displayed and more familiar measure of metabolic control than glycohemoglobin. The lack of a coincidental greater decline in glycohemoglobin level or weight by the patients in the group management program suggests that the decline in serum glucose was sporadic and timed to coincide with the days the subjects met to discuss their progress. Peer pressure may have encouraged timed appropriate behaviors in terms of metabolic control, but the behavioral change was not sustained. The fact that in the experimental group the initial glycohemoglobin level had decreased only 12.5% by the end of the study and that only three patients attained a normal glycohemoglobin concentration at the end of the study indicates that better management techniques need to be developed.

Although knowledge about the disease and its management increased, there was no significant difference in knowledge gain regardless of whether the subjects received lectures from clinical experts or whether they learned from each other. In addition, the amount of knowledge the subject had was not correlated with the initial glycohemoglobin level or with the changes in glycohemoglobin level during the study. Although knowledge may be necessary, it is not a sufficient factor to ensure that patients will successfully manage their own care. The failure to associate knowledge of the disease or its treatment with the effectiveness of the treatment regimen is neither new nor surprising.[17-19]

There was a significant relationship between the number of meetings attended and reduction in glycohemoglobin. In addition, graphs of blood glucose and glycohemoglobin values for the total sample demonstrated a substantial decline while the subjects were meeting weekly or biweekly, followed by a leveling off as the interval between meetings was lengthened. This might be attributable to the effectiveness of frequent meetings or to a gradual waning in the effectiveness of the treatment programs with time. These results must be explored more fully, but when viewed in the light of the limited effectiveness of routine clinic visits at our medical center, which range from monthly to biannually, it seems to indicate that some obese patients with NIDDM may require more frequent and consistent attention to effect change. At the same time, patients may not require the direct supervision or teaching that can only be provided by an experienced health care provider. In times in which cost-containment policies are reducing health care provisions, other alternatives must be explored that have the potential for achieving therapeutic goals at a lower cost. Self-help groups, meeting on a regular basis, for which a health care provider serves as organizer and consultant might prove to be beneficial and cost efficient.

The patient's internal health locus of control was significantly and negatively related to initial glycohemoglobin value. In addition, the more internal the individual's locus of control, the greater the tendency for reduction in glycohemoglobin in response to treatment. Alogna[20] earlier reported that obese patients with NIDDM who were compliant tended to have more of an internal locus of control than noncompliant patients. Wallston and Wallston[21] reviewed evidence that people who have an internal health locus of control (believe their health is the result of their own doing) are more likely to seek information and engage in preventive behavior than those with an external orientation. What is it about health locus of control that allowed internal-approach subjects to be more successful in reducing their glycohemoglobin? Is health locus of control a relatively stable personality trait, or can external-thinking persons be taught to become internal? On the basis of these results, a new study has been implemented in which experimental subjects will undergo treatment in an attempt to strengthen their internal locus of control. The effect of this program on their metabolic control will be examined.

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