Longitudinal Study Of A Diabetes Education And Care Intervention: Predictors Of Improved Glycemic Control

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Abstract: ***Background:*** **This study prospectively identifies those characteristics of office patients with diabetes that predict subsequent improvement in glycemic control in response to an educational intervention.**

Methods: **Data on demographic factors, disease characteristics, and glycemic control were obtained on a consecutive series of patients referred by their primary physician to a 4-day outpatient diabetes education and care program. Follow-up measurement of glycosylated hemoglobin (HbA_{1C}) was obtained from the same laboratory 2 months later. Analysis using logistic response models identified baseline characteristics associated with improved HbA_{1C}.**

Results: **Among the 169 study subjects, 74 (44 percent) had at least a 20 percent improvement in HbA_{1C} levels 2 months after the program. Among these subjects, mean HbA_{1C} level was 10.6 percent before and 7.4 percent 2 months after the program. Factors associated with improvement in HbA_{1C} values in bivariate and multivariate logistic models included duration of diabetes less than 2 years (risk ratio = 1.90, 95 percent confidence interval (CI) 1.30–2.76) and initial HbA_{1C} level greater than 10 percent (risk ratio = 2.75, 95 percent CI 2.08–4.01). Baseline functional status, health locus of control, social support, knowledge of diabetes self-care, age, weight as percentage of ideal body weight, age at diagnosis, race, sex, family history of diabetes, type of diabetes, and mode of treatment were not significant predictors of improved HbA_{1C}.**

Conclusions: **Patients with shorter duration of diabetes and poor baseline glycemic control were most likely to have clinically significant glycemic responses to this program. Severity of disease and regression to the mean were unable to account for this association, leaving unanswered the question of the mechanism of this association. The data also identified a group of patients who do not respond well to this educational approach and for whom novel approaches to behavior change should be considered. (J Am Board Fam Pract 1992; 5:381-7.)**

Diabetes patient education is considered a standard part of diabetes care by clinicians and experts.[1,2] Randomized trials of the efficacy of diabetes patient education, however, have generally shown little[3-7] or no[8-10] sustained beneficial effect on metabolic control. Subjects enrolled in these efficacy studies differ in important ways from patients in office practice who voluntarily enroll in diabetes patient education programs. It can be argued that it is the *effectiveness* of diabetes patient education in such office patients, rather than its *efficacy* in randomly assigned, possibly unmotivated patients, that is of major concern to clinicians. Insufficient data are currently available to characterize predictors of response to diabetes education and care programs among populations of patients in office practice who are motivated enough to attend such programs voluntarily. Why do some patients have marked improvement in glycemic control while others do not?[2,11,12]

To identify factors predictive of clinically meaningful improvement in glycemic control, defined a priori as a 20 percent or more drop in

Submitted, revised, 9 March 1992.

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This work was supported by the Saint Francis Hospital and Medical Center Foundation, the American Academy of Family Physicians Foundation, and the US Public Health Service. The views and opinions expressed in this article do not necessarily reflect those of the sponsors.

glycosylated hemoglobin (HbA_{1C}) among such patients, we conducted a prospective descriptive study of a consecutive series of patients referred by their primary physician to an outpatient diabetes education and care program. We measured demographic, disease-related, and psychosocial variables at the time of enrollment to the program that might be predictive of subsequent clinically significant improvement in glycemic control. The results can be applied by primary physicians to identify prospectively the subset of adult diabetic subjects most likely to benefit from referral to such an integrated program.

Methods

Study Site and Study Subjects

The Diabetes Care Center at Saint Francis Hospital and Medical Center in Hartford, CT, is a referral program providing diabetes education and care. Each week the 4-day third-party reimbursable program enrolls 6 to 8 patients referred by their primary physicians. The program provides (1) individual and small-group instruction and demonstration of current techniques of self-care of diabetes, (2) monitoring of daily blood glucose profiles with initiation or adjustment of therapy as necessary, and (3) articulation of a behaviorally oriented individualized treatment plan based on input from the patient, the diabetes team, and the primary physician.[13] The goals of the program are improved glycemic control and optimal psychological and social adjustment of the patient to life with diabetes. Included in the program staff are a diabetologist, a dietician, 2 certified diabetes educators, a podiatrist, and a social worker. Emotional support of the patient and involvement of the patient's spouse or significant other are emphasized. Patients receive follow-up care by the program staff 2 months after conclusion of the program and then return to the ongoing care of their primary physician. The program philosophy is based on the principles of patient care and education advanced by the American Diabetes Association,[14] which has accredited this program.

All 291 patients with uncontrolled diabetes ($HbA_{1C} \geq 6$ percent) attending the educational program during a 16-month period were eligible for inclusion in the study. Seventeen were excluded from the study because they did not have a baseline HbA_{1C} measurement from the same laboratory as other patients. All the remaining 274 patients gave written informed consent to participate in the study and completed the education and care program; however, 13 were dropped from the analysis because they returned for their follow-up visit either too soon (earlier than 6 weeks) or too late (later than 12 weeks), and 92 failed to return to the same laboratory for their follow up HbA_{1C} measurement. Variation in laboratory standards and methods for doing the HbA_{1C} assay precludes the inclusion of these laboratory values in the statistical analysis. The 169 remaining patients (62 percent) who had their 2-month follow-up HbA_{1C} measured at the same laboratory, and who met inclusion criteria, were designated participants and provided the basis of the analysis.

Data Collection and Variable Definition and Measurement

Data were obtained for all study subjects from interviews, blood tests, and medical records. Glycosylated hemoglobin was assayed in the Saint Francis Hospital and Medical Center special chemistry laboratory using a high-pressure liquid chromatography method,[15] with a normal range of 3.9 percent to 5.9 percent, which did not vary during the study period. The dependent variable, improved glycemic control, was defined as a 20 percent or greater improvement in HbA_{1C} levels during the 2-month follow-up period or having a follow-up HbA_{1C} level of less than 6 percent. This dependent variable was designed a priori to provide a clinically meaningful measure of response or nonresponse, because smaller degrees of glycemic response might not justify the effort and expense involved in the educational intervention.

Data obtained by structured interview at enrollment in the program included measures of functional health status, family function and social support, health locus of control, knowledge of diabetes, and family history of diabetes. We hypothesized that social and personality factors would be as important as medical factors in predicting response to the program.

The Duke-UNC Health Profile[16] was used to measure functional status in four dimensions: physical function, social function, emotional function, and symptom status. Scales for each dimension range from 0 to 1, with 1 indicating better function.

Family function and social support were measured using a standardized instrument that included a combination of items from other family function and social support scales.[17] Values range from 0 to 1, with higher scores indicating better family function and more social support.

The health locus of control measure (HLOC) was obtained using a standardized structured questionnaire.[18] Values range from 0 to 1, with a higher score indicating a more internal locus of control. Subjects with internal HLOC are considered more self-directed and internally motivated with respect to health issues than subjects with external HLOC, who are considered more passive.

The Rand Knowledge of Diabetes Scale[19] was modified for purposes of this study to reflect recent technical advances in the care of diabetes, such as self-monitored blood glucose. Scales range from 0 to 1, with higher scores indicating superior knowledge of practical diabetes care issues.

Family history of diabetes was ascertained from interviews and defined as having a parent, sibling, or child with diabetes. Other data, including the patient's sex, age in years at enrollment in the program, duration of time from the diagnosis of diabetes, age at the time of diabetes diagnosis, weight as percentage of ideal body weight, mode of treatment before and after the program (insulin versus other), and other medical information, were abstracted from medical records.

Analysis of Data

In bivariate analysis, logistic regression was used to assess the relation between each independent variable and improvement in glycemic control. Risk ratios and 95 percent confidence intervals (CIs) were calculated from beta coefficients and standard errors. Multivariate logistic regression models were constructed on the basis of bivariate analysis to assess further the relations among independent variables and improvement in glycemic control. The methods of Kleinbaum, et al.[20] were used to construct these models and to assess interaction terms.

Independent variables considered in the analysis included functional health status, family function and social support, health locus of control, knowledge of diabetes, and family history of diabetes, which were scored as described above. Additional independent variables were categorized, a priori for ease of clinical interpretation, as follows: duration of diabetes less than 2 years versus 2 years or more, age at diagnosis younger than 40 years versus diagnosis at 40 years or older, age younger than 60 years versus 60 years or older, weight less than 120 percent of ideal body weight versus 120 percent of ideal body weight or more, mode of treatment as insulin versus other, race as white versus nonwhite, and baseline HbA_{1C} level of less than 10 percent versus 10 percent or more at the time of enrollment in the program. The results reported used these variable categories; however, parallel models using continuous scoring of appropriate variables yielded the same results. Because of the large number of comparisons analyzed (a total of 14 independent variables were analyzed), the Bonferoni method of correcting for multiple comparisons was used, and the alpha level for significance was adjusted to an alpha of 0.0025 in bivariate analysis.

Results

Among the 169 participants, 55 percent were women and 67 percent were white. Mean age was 55 years and mean duration of diabetes since diagnosis was 7.6 years. Eighty-three percent of the subjects had some improvement in HbA_{1C} levels at the 2-month follow-up, with 44 percent improving their HbA_{1C} levels at least 20 percent or reaching a level less than 6 percent.

Among the 74 subjects who improved at least 20 percent, the mean HbA_{1C} level at baseline was 10.6 percent and mean HbA_{1C} level at the 2-month follow-up was 7.4 percent. Among the remaining 95 subjects, the mean baseline HbA_{1C} level was 8.9 percent, and the 2-month follow-up level was 8.3 percent.

All eligible subjects, including all who were subsequently excluded from analysis, had baseline interviews and HbA_{1C} measurements. There were no significant differences between the study participants and those excluded with respect to baseline HbA_{1C} level, mean age, duration of diabetes, health locus of control, knowledge of diabetes, social support, functional status measures, or other variables (Table 1).

Independent variables were assessed for multicollinearity, and moderate correlation was noted between duration of diabetes and age ($r = 0.34$),

Table 1. Comparison of Study Participants (n = 169) with Subjects Who Failed to Return for Follow-Up Glycosylated Hemoglobin Measurements to the Same Laboratory or Who Returned at an Inappropriate Time (n = 105).*

Variable	Study Participants Mean (± SEM)	Dropouts and Excluded Subjects Mean (± SEM)
Mean age (years)	55.2 (± 1.2)	55.2 (± 1.5)
Women (%)	55	54
White (%)	67	58
Mean duration of diabetes (mo)	91.2 (± 7.9)	95.5 (± 10.9)
Mean baseline glycosylated hemoglobin (%)	9.7 (± 0.16)	9.2 (± 0.18)
Health locus of control	0.53 (± 0.08)	0.54 (± 0.11)
Family function	0.79 (± 0.01)	0.78 (± 0.02)
Knowledge	0.64 (± 0.01)	0.65 (± 0.02)
Functional status — physical	0.64 (± 0.01)	0.62 (± 0.02)
Functional status — social	0.67 (± 0.02)	0.67 (± 0.03)
Functional status — emotional	0.75 (± 0.01)	0.73 (± 0.02)
Functional status — symptoms	0.77 (± 0.01)	0.75 (± 0.02)

*All differences are statistically nonsignificant ($P > 0.05$).

female sex and weight index ($r = 0.44$), and baseline HbA_{1C} and follow-up HbA_{1C} levels ($r = 0.57$).

Bivariate logistic response models showed that study subjects who had a shorter duration of diabetes ($\chi^2 = 12.5$, $df = 1$, $P = 0.0004$) and those who had a baseline HbA_{1C} level greater than or equal to 10 percent ($\chi^2 = 31.3$, $df = 1$, $P = 0.0001$) were significantly more likely to have a 20 percent or more improvement in HbA_{1C} levels at the 2-month follow-up. Other variables, including age, sex, race, weight index, family history of diabetes, age at diagnosis, mode of treatment, health locus of control, functional status, and family function were not predictive of improved glycemic control (Table 2) when using the alpha level corrected for multiple comparisons ($\alpha = 0.0025$).

Multivariate logistic response models were constructed to assess which variables and interaction terms best predict a 20 percent or greater improvement in HbA_{1C} levels 2 months after the educational intervention. In these models, only duration of diabetes of 2 years or less (risk ratio = 1.90, 95 percent CI 1.30–2.76) and baseline HbA_{1C} level of 10 percent or more (risk ratio = 2.75, 95 percent CI 2.08–4.01) predicted improvement. No other variables contributed additional predictive value to the model once these two variables were entered. Assessment of interaction terms between these variables and health locus of control, sex, race, and weight index, and a sex by social support interaction term showed that no such terms individually or in aggregate significantly improved the main effects model.

Table 3 illustrates the clinical implications of these data by showing the number of subjects who did and did not improve their HbA_{1C} levels at least 20 percent in relation to entry HbA_{1C} levels and duration of diabetes. It can be seen that 23 of 27 subjects (85 percent) who had initial HbA_{1C} levels of 10 percent or more and whose diabetes was diagnosed within 2 years significantly improved as did 21 of 36 subjects (58 percent) with HbA_{1C} levels of 10 percent or more who had diabetes longer than 2 years. Only 25 of 94 subjects (27 percent) with HbA_{1C} levels less than 10 percent at baseline improved significantly 2 months after the program. Within this group, more of those who had diabetes for 2 years or less improved (14 of 32, 44 percent) than those with diabetes longer than 2 years (11 of 62, 18 percent).

Table 2. Bivariate Association of Independent Variables with Improvement in Metabolic Control among Study Participants (n = 169).

Variable	Logistic Chi-Square	*P* Value
Glycosylated hemoglobin at baseline > 10%	31.30	0.0001*
Duration of diabetes < 2 yr	12.50	0.0004*
Age	1.24	0.26
Sex	2.36	0.12
Race	4.30	0.04
Weight index	2.44	0.12
Age at diagnosis	0.27	0.61
Mode of treatment	0.50	0.48
Family history of diabetes	1.52	0.22
Health locus of control	3.00	0.08
Family function	0.03	0.87
Knowledge	1.49	0.22
Physical function	0.06	0.81
Emotional function	0.00	0.95
Symptom function	0.23	0.63

Note: Logistic modeling of data with dependent variable as 20 percent or greater improvement in glycosylated hemoglobin (HbA_{1C}) versus less than 20 percent improvement in HbA_{1C}.
*Statistically significant at the alpha level of 0.0025 set for significance using the Bonferroni adjustment for multiple comparisons.

Table 3. Glycemic Control Changes in Study Subjects by Baseline Glycemic Control and Duration of Diabetes (n = 157 with complete data).

Baseline Glycemic Control	Duration of Diabetes	Outcome		
		< 20 Percent Improvement in HbA_{1C} Levels	> 20 Percent Improvement in HbA_{1C} Levels	Percent Improved
HbA_{1C} > 10%	< 2 yr	4	23	85
	≥ 2 yr	15	21	58
HbA_{1C} < 10%	< 2 yr	18	14	44
	≥ 2 yr	51	11	18

HbA_{1C} = Glycosylated hemoglobin.

Because subjects with higher baseline HbA_{1C} levels had more improvement, regression to the mean was considered as a possible explanation of the results. Table 4 shows there were few subjects with very high baseline HbA_{1C} levels, and that response to the program was encouraging in all baseline HbA_{1C} classifications. Among subjects whose baseline HbA_{1C} level was relatively low (6 to 8 percent), more than 60 percent showed some improvement in HbA_{1C} at follow-up. Furthermore, if regression to the mean were operating on the basis of measurement error, low baseline HbA_{1C} levels would be expected to rise toward the mean, just as high baseline HbA_{1C} levels would be expected to drop toward the mean; there was little evidence of such movement in these data.

Table 5 illustrates the proportion of subjects within each of three baseline HbA_{1C} groups who changed glycemic control categories as defined by the American Diabetes Association. Overall, 59 percent of all subjects showed improvement by this clinical classification scheme, while 4 percent were worse, and 37 percent had no change. The specific target HbA_{1C} level for a particular patient can vary, but in these patients, 55 percent had HbA_{1C} levels below 8 percent, and 92 percent had HbA_{1C} levels below 10 percent at follow-up, while those with HbA_{1C} levels below 10 percent decreased from 40 percent at baseline to 8 percent of subjects at follow-up.

Table 4. Distribution of Study Subjects by Baseline Glycosylated Hemoglobin, Showing Proportion Who Showed Any Improvement in HbA_{1C} Levels at Follow-Up and Proportion Who Improved HbA_{1C} at Least 20 Percent.

Percent Baseline HbA_{1C}	No.	Percent Who Showed Any Improvement at Follow-Up	Percent Who Showed ≥ 20 Percent Drop at Follow-Up
≥ 6 ≤ 8	39	61.5	25.6*
> 8 ≤ 10	63	84.1	27.0
> 10 ≤ 12	51	96.0	64.7
> 12 ≤ 14	9	88.9	77.8
> 14	7	100.0	100.0

*Ten subjects in this group had a follow-up HbA_{1C} reading that was ≤ 6 percent.

Discussion

These data provide clinicians with a method for estimating the likelihood that a particular adult patient with diabetes will derive clinical benefit from this particular type of diabetes education and care program. The data identify two significant predictors of favorable response to the program: duration of diabetes of less than 2 years from diagnosis, and HbA_{1C} levels of 10 percent or more at entry to the program.

Table 5. Distribution of Study Subjects by Initial and Subsequent Glycosylated Hemoglobin, Using a Modification of the American Diabetes Association's Metabolic Control Classification.

Initial HbA_{1C}	Follow-Up HbA_{1C}			No.	Percent Improved
	Good	Fair	Poor		
Good (≤ 8%)	37*	2	0	39	26
Fair (> 8–< 10%)	32	27	4	63	51
Poor (≥ 10%)	24	34	9	67	87
Total	93	63	13	169	59

*Of the 39 subjects who started with HbA_{1C} < 8%, 10 had follow-up HbA_{1C} ≤ 6%.

While these data indicate a definite benefit of this type of program to recently diagnosed, poorly controlled patients with diabetes, the mechanism by which this benefit might be conferred is not apparent. Furthermore, the data imply that alternative behavioral change strategies might be necessary for patients who have diabetes for longer periods of time, although the data are too limited to indicate how such novel strategies could be developed.

These data confirm the usefulness of early referral of diabetic patients to appropriate diabetes

education and care programs in improving glycemic control. Patients whose diabetes was recently diagnosed were clearly more responsive to the program although the reasons for this response remain unknown. Because baseline HbA_{1C} levels did not vary with duration of diabetes ($\chi^2 = 1.25$, $P = 0.26$), and because subjects with higher HbA_{1C} levels at baseline were most likely to have a positive response to the program, it is unlikely that increasing severity of disease is a major explanation of the lack of glycemic improvement in patients with longer duration of diabetes. Although insulinopenia can progress with time, only 7 percent of subjects were thought to be on therapy that was not potentially efficacious at the time of enrollment in the program. Further research might usefully attempt to identify what disease-related or psychosocial factors might explain this variation in response with duration of diabetes and to learn whether periodic repetition of such a program could be of benefit and for whom.

The other significant predictor of glycemic improvement was poor baseline glycemic control. The dependent variable was defined as a percentage improvement from baseline, rather than as an absolute drop in HbA_{1C} level, so that subjects with higher baseline HbA_{1C} levels would not have an inflated chance of improvement. Higher baseline HbA_{1C} levels predicted positive response to the program independent of duration of diabetes: 70 percent of those with baseline HbA_{1C} levels of 10 percent or more versus only 36 percent of those with baseline HbA_{1C} levels lower than 10 percent improved.

Why might high baseline HbA_{1C} levels be predictive of improvement? Perhaps the subjects with worse control more often had easily remediable deficits in self-care behaviors. There was no association, however, between knowledge of self-care behavior at baseline and change in HbA_{1C} levels. Because the program included consultation with a diabetologist and treatment was adjusted as indicated, some patients with poor initial glycemic control who were not on appropriate therapy had their therapy changed by the diabetologist. Major changes in treatment (such as initiation of insulin treatment) were made in 7 percent of all cases and in 11 percent of patients with initial HbA_{1C} levels of 10 percent or more. It is unlikely that other major changes in treatment were made independently by the primary physician within the 2-month follow-up period. Specific data on changes in diet or exercise level were not collected, but such change could have mediated the change in HbA_{1C} levels.

There are several limitations of this study. The study was an observational one and was neither randomized nor controlled. It is possible that the observed changes in glycemic control were due to factors other than the education and care program. The study patients were referred to the program and were not representative of all patients with diabetes. The particular program evaluated could have unique features that limit the generalizability of the results to other types of programs.[13,14] The self-report measures used to assess functional status, locus of control, and family and social support have been evaluated in other studies, but not specifically for diabetic persons. Observational methods of functional assessment and diabetes-specific measures of social support, family function, and locus of control should be considered for use.

Despite these limitations, we believe that the study results are interesting and important. The study explored a relatively rich matrix of clinical, demographic, and psychosocial data and identified two specific factors that allow estimation of an individual patient's likelihood of favorable response to an integrated diabetes education and care intervention. The results extend the work of others[21] and indicate that the patients most likely to benefit are those with shorter duration of diabetes (less than 2 years) who have poor baseline glycemic control (HbA_{1C} more than 10 percent). From these results it is apparent that there is an urgent need to develop a theoretical model that will lead to novel educational and clinical strategies aimed at improving control in those patients who have had diabetes for longer periods of time and in whom behavioral changes necessary for improvements in glycemic control and other health outcomes have been difficult to effect.

Our special thanks to Dr. William L. Miller for his comments and suggestions. We also appreciate the contributions of Ms. Remy McCormick in data collection and of Ms. Kelly Hookstadt in data processing and data management.

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