Metabolic Control in Non-Insulin-Dependent Diabetes Mellitus: Factors Associated With Patient Outcomes

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We conducted a cross-sectional study to assess the association of various demographic and medical-care variables with metabolic outcomes in non-insulin-dependent diabetic subjects. The study population was representative of the diagnosed care-seeking diabetic population of a defined geographic community on the Navajo reservation in Arizona. The dependent variable metabolic control was measured as the mean of all random plasma glucose values obtained only at scheduled diabetes clinic visits over 2 yr.

Multivariate analysis of the data showed that better metabolic control was most strongly associated with compliance with scheduled appointments. Mode of treatment was also associated with metabolic control. Other variables tested, including source of care, age, sex, duration of diabetes, presence of complications, and weight change, were not associated with metabolic control.

The strongest analysis of covariance model with demographic and medical-care variables accounted for 39% of the variance in metabolic control. The analysis suggests that other variables, possibly including several psychosocial variables, need to be assessed for their contribution to metabolic control.
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Clinicians who care for patients with diabetes know this is a most vexing disease that is very difficult to treat. Since the introduction of insulin in 1922, medical scientists have produced an ever-accelerating parade of technological advances for the treatment and control of this disease. Yet, based on a review of reports from primary-care settings, less than half of adults with diabetes are in "acceptable" metabolic control (1–13). Even more provocative are the reports by Romm and Hulka (1,2) that the process of care for diabetes in several practice settings seems to be unrelated to metabolic control of the disease.

We investigated the association of process of diabetic care with metabolic outcomes of the disease in a population-based random sample of Navajos with non-insulin-dependent diabetes mellitus (NIDDM). We hypothesized that variables such as mode of treatment, compliance with care, and source of care are associated with metabolic outcomes of the disease, even when controlling in the analysis for potentially confounding variables such as age, sex, duration of disease, presence of complications, and weight change.

MATERIALS AND METHODS

Site of study. This study was conducted in the Tuba City Service Unit of the Navajo Indian Reservation in Arizona. The population of 18,700 is served by only two sources of outpatient care: both are Indian Health Service clinics. At each clinic, patients with diabetes are seen an average of once every 2–3 mo in an organized diabetes clinic. Services are provided by physicians of different specialties at the two clinics, and same-day plasma chemistry results are available at one of the clinics. The services of public-health nurses, health educators, dietitians, ophthalmologists, and physical therapists are available to patients from both clinics.

Services and medications are offered to Native American patients without charge. Other sources of medical care are at least 80 miles away in Flagstaff or Page, Arizona. Inquiries of health-care providers at these towns reveal that no patients with diabetes who reside in the Tuba City Service Unit are known to get routine care there. Therefore, these Indian Health Service clinics apparently provide routine care to all subjects with the diagnosis of diabetes who live in this geographic area and receive medical care.

Sample selection. All patients in the service unit who had the diagnosis of NIDDM were identified in November 1984. Patients with insulin-dependent diabetes mellitus and patients who failed to meet American Diabetes Association criteria for diagnosis of NIDDM were excluded (14). A patient was required to have attended one or the other diabetes clinic on at least two occasions during the previous 2 yr to be included in the study.

The inclusion criteria identified 439 eligible subjects at the central clinic. From this list, a sample of 66 subjects was selected from a table of random numbers. The inclusion criteria identified 20 eligible subjects at the satellite clinic; all of these subjects were included in the study.

Data collection. The medical record of each subject was retrospectively reviewed over 2 yr (November 1982 to November 1984), and pertinent data were abstracted. Plasma glucose levels obtained only at the time of scheduled diabetes clinic visits were included and identified as either fasting plasma glucose or random plasma glucose from notations in the records. Other data collected included demographic data, date of the original diagnosis of NIDDM by American Diabetes Association criteria (14), mode of treatment during the 2-yr study period (diet only, diet and oral hypoglycemic agent, or diet and insulin therapy), number and causes of hospitalizations, number of kept and missed diabetes clinic appointments, and weight change during the study period.

In addition, the presence or absence of certain diabetic complications was noted. Nephropathy was considered present if the plasma creatinine level was >2 mg/dl or if proteinuria of ≥2+ was present on at least two occasions in the absence of a urinary tract infection. History of a myocardial infarction (typical pain and either positive cardiac isoenzymes or positive electrocardiographic evidence of infarction with a concurrent hospital admission), presence of angina, or abnormal electrocardiogram (conduction defect greater than first degree, Q waves, or complex ventricular or atrial arrythmias) was noted. Nontraumatic amputations and clinical diagnosis of a cerebrovascular accident were recorded. It was felt that the presence of neuropathy or retinopathy could not be evaluated adequately on the basis of available data.

Variable definition. The principal dependent variable of interest is metabolic control of NIDDM. In this study the mean value of all random plasma glucose values obtained over 2 yr at a time of scheduled diabetes clinic visits is used as the index of metabolic control. Fasting plasma glucose values were available on 62 of the 86 study subjects, whereas 85 subjects had multiple random plasma glucose values available for analysis. Use of mean random plasma glucose values is an imperfect measure of metabolic control; unfortunately, only 2 of the 86 subjects included in this study had available glycosylated hemoglobin values.

The principal independent variables of interest were source of medical care, mode of treatment, and compliance with appointments (calculated as the ratio of appointments kept to appointments scheduled over the 2-yr period). Other independent variables were considered as covariates or potential confounding variables. These include age, sex, duration of disease, weight change, hospitalization rates, and complications (as defined above).

TABLE 1
One-way analysis of variance showing mean random plasma glucose values as a function of nominal independent variables

Nominal independent variable	*n*	Mean random plasma glucose (mg/dl)	*F*	df	*P*
Sex					
Male	35	251	0.31	1,81	.58
Female	48	240			
Treatment					
Diet alone	17	170			
Oral agent and diet	45	256	10.89	2,80	.0001
Insulin and diet	24	279			
Clinic site					
Central clinic	66	249	0.95	1,81	.33
Satellite clinic	20	227			
Complications					
Any complications	38	241	0.08	1,81	.78
No complications	45	247			
Metabolic control*					
Acceptable	27	172	(mean random plasma glucose values used to define these categories)		
Fair	26	238			
Poor	30	316			

F and *P* values are from one-way analysis of variance.
*Metabolic control categorized as acceptable, fair, or poor by American Diabetes Association criteria (14).

Method of analysis. Analysis of data was done in two steps. In the first step, bivariate associations were evaluated with analysis of variance and simple linear regression. Choice of test depended on the measurement level of the variables being compared (15).

Based on associations observed in bivariate analyses, a multivariate model was constructed. Analysis of covariance was considered best for this task, because it allowed control of the effect of an interval level covariate while considering nominal independent variables (16,17).

RESULTS

The mean number of random plasma glucose values obtained at scheduled diabetes clinic appointments was 7 per study subject with a range of 3–15. Three subjects had missing values for one or more independent variables and were therefore excluded from certain analysis of variance procedures.

Table 1 shows data on the bivariate associations of metabolic control with the ordinal variables: sex, mode of treatment, clinic site, complications, and metabolic control. Table 2 shows data on the bivariate associations of metabolic control with the interval-level variables: mean age, duration of diabetes, weight change, and compliance with appointments. Mode of treatment (F = 10.89; df = 2,80; $P <$ .0001) and compliance with appointments (F = 19.73; df = 1,81; $P <$ .0001) were significantly associated with metabolic outcome in the bivariate analyses. Demographic variables such as age (F = 0.85; df = 1,81; P = .36) and sex (F = 0.31; df = 1,81; P = .58) were not associated with metabolic control. Disease-related factors, such as duration of disease from time of diagnosis (F = 0.02; df = 1,80; P = .88), mean weight change (F = 1.01; df = 1,73; P = .32), and presence of complications (F = 0.08; df = 1,81; P = .78), were not associated with metabolic control. In addition, source of medical care (F = 0.95; df = 1,81; P = .33) was not significantly associated with metabolic control in bivariate analysis.

An analysis of covariance model found that metabolic outcome was associated with compliance with appointments (F = 25.07; $P <$ .0001) and mode of treatment (F = 10.63; $P <$ .0001) but not with source of medical care (F = 3.65; $P <$ .06) or other variables studied. The first three variables that entered the model—compliance with scheduled appointments, mode of treatment, and source of medical care—accounted for 39% of the variance in metabolic control.

TABLE 2

Associations between selected variables and metabolic control

Interval-level variable	Metabolic control classification by American Diabetes Association criteria: Poor	Fair	Acceptable
Mean age (yr)	63	72	59
Mean duration of diabetes from time of diagnosis (yr)	8.0	7.8	6.3
Compliance with diabetes clinic appointments*	0.68	0.76	0.81
Mean weight change (lb)	−4.2	+0.07	+1.2

Tests of statistical significance were calculated with linear regression on actual plasma glucose values and are given in RESULTS.

*Calculated as number of diabetes clinic appointments attended divided by total number of diabetes clinic appointments scheduled.

DISCUSSION

This study demonstrates that the metabolic control of NIDDM in Navajos is associated with several variables. The first of these is compliance with scheduled diabetes clinic appointments. This variable was designed as a measure of compliance with care in general, because direct measurement of compliance with diet, oral hypoglycemic agents, or insulin treatment is very difficult to assess. Compliance with appointments may be a reliable approximation of other types of compliance. However, a plausible alternative hypothesis is that patients with higher compliance with appointments have a better patient-physician relationship (18,19), are more knowledgeable about their disease, are psychologically better adjusted to their disease, or experience greater social or family support (20–22).

The second variable associated with metabolic control is mode of treatment. Patients treated with diet alone had a mean random glucose of 169 mg/dl, whereas patients on oral agents averaged 256 mg/dl and those on insulin averaged 278 mg/dl. This observation may reflect the common clinical practice of placing patients in poorer control on more aggressive therapies rather than reflecting the competing hypothesis that patients treated with more aggressive therapies have worse metabolic control. However, there are insufficient data available from this cross-sectional study to elaborate on this point.

The third variable that enters the model—source of medical care—is not associated with metabolic outcome (P = .06). Patients attending the central clinic (with more specialized physicians and more sophisticated laboratory tests available) averaged a random plasma glucose value of 249 mg/dl (95% confidence interval 229–269 mg/dl), whereas those attending the satellite clinic averaged 227 mg/dl (95% confidence interval 183–271 mg/dl). The two groups of patients attending different clinics were not significantly different on any other variable, including age, hospitalization rate, mode of treatment (P = .105, Fischer's exact 2-tailed test), complication rate, or other variables. We conclude that the metabolic control achieved by patients attending the two clinics appears to be without significant difference. Power analysis done at the time the study was planned showed this study had >80% probability of detecting a true difference of 50 mg/dl between the two clinics if such a difference actually existed (23).

The analysis of covariance model accounts for 39% of the variance in mean random plasma glucose observed in the study subjects (r^2 of model = .39). Thus, although the model is able to account for some of the variance in metabolic control, a substantial proportion of the variance in metabolic control is not explained by the independent variables measured in this study. In fact, compliance with appointments, which is the strongest variable in the model, may depend more on psychosocial factors than on biomedical factors (18–20). Our data suggest that future work on metabolic outcomes among diabetic patients might profit from a sharper focus on variables such as social network, social support, and family function (21,22,24).

We conclude that the process of medical care in this study is related to metabolic outcomes of diabetic subjects only to a limited extent. The variable most strongly related to outcome is compliance with appointments. However, this variable may be more reflective of social or psychological factors than medical factors. Mode of treatment was related to outcome in the manner that would be predicted. Patients in poorer control were being treated more aggressively, but the cross-sectional study design does not permit speculation as to whether more aggressive treatments improved metabolic control. Finally, the source of medical care was not related to metabolic outcomes, despite the more specialized providers and more sophisticated laboratory services available at one of the clinics.

Our data are consistent with the findings of Romm and Hulka (1), who concluded that differences in the process of care may not be associated with differences in metabolic outcome among diabetic patients. Better understanding is needed of how social and psychological factors are related to metabolic outcomes in a series of such patients. This is an area that has received insufficient attention from researchers (24,25). Social and psychological factors may be as strongly associated with metabolic outcomes as medical factors are (24). Such social and psychological factors might be amenable to interventions that could reduce costs of care (26) while maintaining or improving outcomes (19,20). Studies that examine both medical and nonmedical variables that affect diabetic control are warranted.

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