Dropout and Relapse During Diabetes Care

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OBJECTIVE — To determine factors associated with dropout and relapse during chronic diabetes care.

RESEARCH DESIGN AND METHODS — Private practice outpatient treatment-education program for adult diabetes was surveyed. Retrospective analysis was done, involving 422 patients for up to 3 yr.

RESULTS — Of the patients in the study, 12% dropped out after the initial visit, and 33% of the residual cohort dropped out during each subsequent 6-mo period. Factors associated with dropout included distance from home to clinic >100 miles, lack of insulin treatment, and cigarette smoking. In patients who remained in follow-up, a significant decrease in HbA_{1C} occurred during the first 6 mo, but 40% of the patients relapsed between 6 and 12 mo. Frequency of relapse declined as time passed. Relapse was more frequent in women.

CONCLUSIONS — Dropout from treatment and relapse after temporary improvement account for a substantial amount of uncontrolled diabetes, and overcoming the obstacles of dropout and relapse has potential for significant improvement in diabetes care.

Over 6 million people in the U.S. have diagnosed diabetes mellitus and presumably are under medical treatment (1,2). One of the generally accepted goals of clinical care of the diabetic patient is control of metabolic abnormalities that predispose to long-term degenerative complications (3–5). Control of hyperglycemia is monitored by the level of HbA_{1C}. In most surveys of diabetic patients, mean levels of HbA_{1C} are in the 8–9% range, indicating a level of chronic glycemia considerably above normal (6,7). Clinical experience has indicated that the level of glycemic control at the onset of study usually can be lowered, at least initially (8). If so, the widespread prevalence of hyperglycemia suggests either that patients have dropped out of effective treatment, or that they have relapsed while continuing to interact with health-care providers.

A structured clinical program that emphasizes near-normal glycemic levels and provides appropriate patient education and nutritional counseling can result in longstanding reduction of HbA_{1C} for a substantial number of patients (6,9,10).

Adhering to these principles in a diabetes-care program, we noted that, in the majority of patients, significant improvement in glycemic control was achieved readily. However, for one reason or another, a substantial proportion of patients dropped out of follow-up. When patients dropped out, it was impossible to obtain follow-up data.

In the patients who remained in follow-up, a subgroup showed initial improvement during the first 6 mo and then tended to relapse as time went on. When patients improved and then relapsed, the potential for subsequent improvement remained, particularly if the causes of relapse could be understood. These observations led us to analyze the factors associated with dropout and relapse during chronic diabetes care.

RESEARCH DESIGN AND METHODS

— The setting for this study was an office-based private endocrinology practice in Nashville, Tennessee, serving patients from both the local metropolitan area and a referral area, which extended into several surrounding counties.

In this retrospective analysis, 422 consecutive adult diabetic outpatients were included. Of the patients, 34% had type I diabetes, and 66% had type II diabetes (11). Mean age at entry was 46 yr, and mean duration of diabetes was 11 yr. Some 71% of the patients were receiving insulin. Detailed characteristics of the patients are listed in Table 1 (12).

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TYPE I DIABETES, INSULIN-DEPENDENT DIABETES MELLITUS; TYPE II DIABETES, NON-INSULIN-DEPENDENT DIABETES MELLITUS; BMI, BODY MASS INDEX; CI, CONFIDENCE INTERVAL.

Table 1—*Characteristics of patients*

N	422
SEX (% MALE)	49%
TYPE I	145 (34%)
BASELINE HbA_{1C} (%)	8.6 ± 1.5
BMI (KG/M^2)	24.8 ± 5
TYPE II	277 (66%)
BASELINE HbA_{1C} (%)	8.5 ± 1.8
BMI (KG/M^2)	30.6 ± 7
AGE AT ENTRY (YR)	46 ± 16
≤18 YR	23 (5%)
19–39 YR	129 (31%)
40–64 YR	216 (52%)
≥65 YR	50 (12%)
DURATION OF DIABETES (YR)	11 ± 9
<1	32 (8%)
1–4 YR	86 (20%)
5–19 YR	240 (57%)
>20 YR	65 (15%)
TREATMENT	
DIET ONLY	18 (4%)
ORAL HYPOGLYCEMIC PILLS	101 (25%)
INSULIN	294 (71%)
HISTORY OF KETOACIDOSIS	54 (13%)
HISTORY OF HYPOGLYCEMIC COMA	50 (12%)
HISTORY OF HYPOGLYCEMIA UNAWARENESS	33 (8%)
CIGARETTE SMOKERS	76 (18%)
OBESE (BMI >27.5)	206 (49%)
SEVERELY OBESE (BMI >31.5)	118 (29%)
DISTANCE FROM CLINIC	
NASHVILLE	155 (37%)
ADJACENT COUNTIES	166 (39%)
FURTHER, BUT <100 MILES	72 (17%)
>100 MILES	29 (7%)

Values for baseline HBA_{1C}, BMI, age at entry, and duration of diabetes are means ± SD. Other values are *n*, with % of total *n* in parenthesis.

Follow-up duration ranged from 3 to 42 mo, with median follow-up of 18 mo. Source of referral, socioeconomic or educational status, and health insurance coverage were variable and were not distinguished in this study.

After clinical history, physical examination, and prescription of medication by an endocrinologist, all patients agreed to enter an ongoing program of medical care, education in self-management of diabetes, and nutritional counseling. The goal of treatment was to achieve a level of chronic glycemic control as close to physiological as possible, without excessive or dangerous hypoglycemia. Therefore, the targets for glycemic control and HbA_{1C} varied according to individual patient situations. Entry into the program, a few weeks after the physician visit, consisted of a 2-h session with a nurse educator and a 1-h session with a dietitian. These encounters were devoted to assessment of individual patient's needs, goal setting, and initiation of instruction and counseling. Education visits with the nurse educator and dietitian usually included participation with other family members. One-to-one instruction was supplemented with visual aides, charts, videotapes, and printed materials for home use. Topics for instruction and prevention were grouped into three major categories: survival skills (insulin injection technique, prevention and treatment of hypoglycemia, and prevention and treatment of ketosis); daily practices (self-monitoring of blood glucose and interpretation, insulin supplements for hyperglycemia, diet, exercise, hygiene, and foot care); and cognitive issues (general understanding of diabetes, prevention of complications, family and personal coping skills, relationship to other health problems, role of hypertension and hyperlipidemias, and appropriate use of the health care system). Topics appropriate for each patient were selected, and the sequence and duration were determined depending on each patient's needs, abilities, and readiness to learn (13). Health beliefs were assessed by questionnaire, and attempts were made to improve beliefs and attitudes that were potentially detrimental to optimal care.

After the initial sessions with the nurse educator and dietitian, patients were instructed to return for 30-min follow-up visits until education was completed, the frequency depending upon individual needs and circumstances. Thereafter, follow-up visits were scheduled every ~3 mo with the physician, nurse educator, dietitian, or combinations of the three as indicated by individual patient needs. Dropout was defined as a permanent lack of follow-up visit with any member of the treatment team. When patients were delinquent in follow-up appointments, efforts were made to contact them via telephone and/or letter. Questionnaires were sent to determine reasons for dropout, and whether care was continued elsewhere; but information gathered by this technique was scanty and of limited value.

HbA_{1C} was measured by a mini-column technique (14), normal range of which was 4.2–6.1%. Baseline HbA_{1C} was obtained at the first visit for patients new to the practice. For patients who had been treated by the physicians in this practice before the onset of the education program, baseline HbA_{1C} was the average of all HbA_{1C} levels obtained before the entry session. Subsequent HbA_{1C} levels were obtained every ~3 mo.

Unless stated otherwise, data are presented as means ± SD. In patients for whom follow-up data were available, Student's *t* test for paired samples was used to determine statistical significance of changes from baseline. The χ^2 test was used to determine significance of differences of frequencies between contingencies. Pearson's correlation coefficient, *r*, was used to express the degree of relationship between two sets of variables.

RESULTS

Dropout immediately after entry

Despite nominal acceptance of the importance of follow-up care, 50 patients (12%) dropped out after the entry visit. Distance from the patients' residence to Nashville was related significantly to frequency of early dropout. Of the 393 patients who lived in Nashville and the 100-mile radius usual referral area of middle Tennessee and southern Kentucky, 43 (11%) dropped out, whereas 7 (24%) of the 29 patients from further distances dropped out. Patients who lived >100 miles from Nashville dropped out at a significantly higher rate

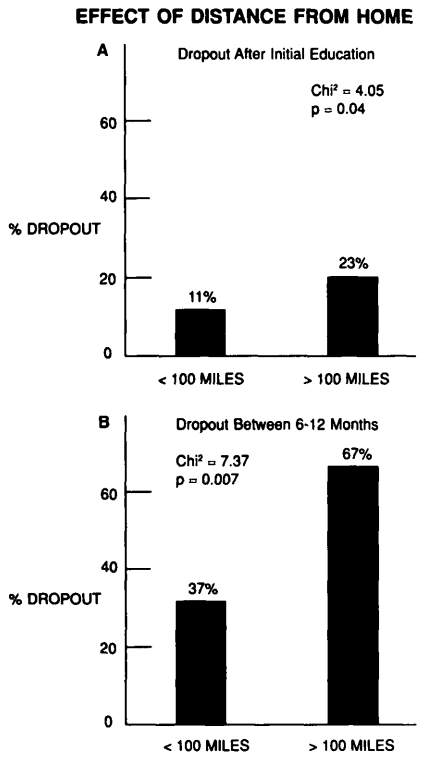

Figure 1—*Patients who lived outside the usual referral area of ~100-mile radius had significantly higher rates of dropout during first 6 mo (A) and during second 6 mo (B).*

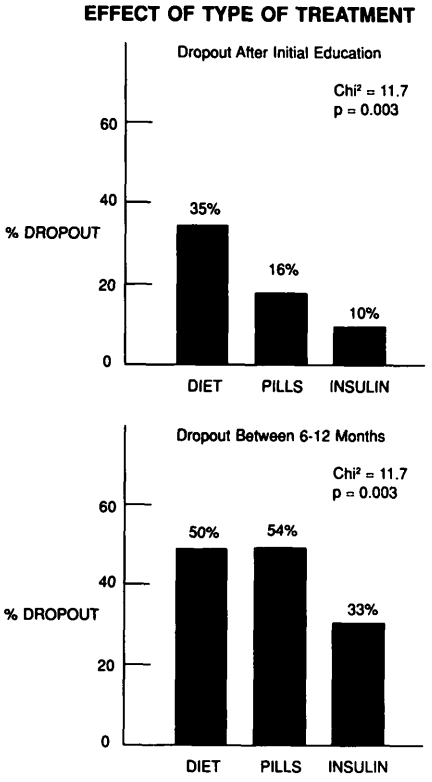

Figure 2—*Patients who received insulin treatment had significantly lower rates of dropout.*

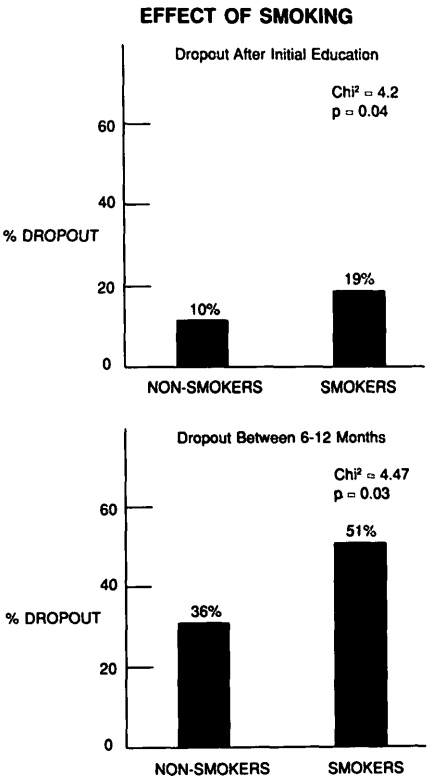

Figure 3—*Patients who smoked cigarettes had significantly higher rates of dropout than nonsmokers.*

than those who lived closer (χ^2 (1), $P = 0.04$), (Fig. 1).

The early dropout rate was 10% in patients treated with insulin, 16% in patients treated with oral hypoglycemic medication, and 35% in patients treated only with diet (χ^2 (2), $P = 0.003$), (Fig. 2).

The early dropout rate was higher in cigarette smokers (Fig. 3). Of the nonsmokers, 10% dropped out after the entry visit, whereas 19% of the cigarette smokers dropped out (χ^2 (1), $P = 0.04$).

We found no association between the early dropout rate and age, sex, duration of diabetes, type of diabetes, BMI, or HbA_{1C} at entry.

Dropout between 6 and 12 mo after entry

Of the original cohort of 422 patients, 372 patients (88%) were still in follow-up at 6 mo after the entry visit. Between 6 and 12 mo after entry, 131 additional patients (35% of those remaining) dropped out. Factors related to dropout were similar to those associated with early dropout, including distance of residence from Nashville, type of treatment, and cigarette smoking (Figs. 1–3, lower panels).

Dropout more than 12 mo after entry

Between 12 and 18 mo after entry, 34% of the residual cohort dropped out. As at earlier times, the frequency of dropout after 12 mo was significantly higher among patients who did not use insulin. In addition, patients whose HbA_{1C} had decreased by at least 1.0% during the first 6 mo and later had relapsed with HbA_{1C} increasing by at least 1.0% during the second 6 mo had significantly higher frequency of dropout after 12 mo than those who had not relapsed.

Decrease from baseline HbA_{1C}

The mean level of HbA_{1C} at baseline was 8.6 ± 1.7. No significant difference in baseline HbA_{1C} was observed between patients with type I and type II diabetes, male and female, nor obese and nonobese patients; and baseline HbA_{1C} was not correlated significantly with age, duration of diabetes, or BMI. After initial treatment and education at entry, a prompt and significant decrease in HbA_{1C} was noted, and patients who remained in follow-up maintained a significant decrease from baseline for as long as 36 mo. During the first 6 mo after entry, the mean absolute change in HbA_{1C} was −0.93 (95% CI = −1.17% to −0.68, $P = 0.0005$). The change in

HbA_{1C} correlated with the level of the baseline HbA_{1C}, $r = 0.68$, $P = 0.005$. Thus, the higher the baseline HbA_{1C}, the greater the initial reduction after beginning this program. The change in HbA_{1C} did not correlate with age, duration of diabetes, BMI, or change in weight in obese patients. No significant difference was observed in the mean change in HbA_{1C} during the first 6 mo between patients with type I and type II diabetes, male and female, nor nonobese and obese patients. Though the tendency was towards an increase in mean HbA_{1C} after 6 mo, the decrease from baseline remained statistically significant throughout; and at 36 mo after entry, the mean absolute change in HbA_{1C} from entry was −0.77 (95% CI = −1.48 to −0.05, $P = 0.04$).

Relapse (failure to maintain reduction in HbA_{1C})

Analysis of relapse was limited to patients taking insulin to have a more homogenous group. Patients with hypoglycemia unawareness were excluded from analysis, because hypoglycemia unawareness changed treatment goals. In patients with hypoglycemia unawareness, an increase in HbA_{1C}, rather than a decrease, was often a desired clinical outcome. In the 136 insulin-treated patients without hypoglycemia unawareness for whom follow-up data were available, the mean absolute change in HbA_{1C} from baseline during the first 6 mo was −0.9, with a range from −6.7 to 3.9. Some 43% had decrease in HbA_{1C} at least 1.0; 19% had decrease in HbA_{1C} at least 2.0; and 14% had decrease in HbA_{1C} at least 3.0.

The occurrence of relapse was defined as follows: if the initial decrease in HbA_{1C} was at least 1.0, a subsequent increase of at least 1.0 was counted as relapse. If the initial decrease in HbA_{1C} was at least 2.0, a subsequent increase of at least 2.0 was counted as relapse, and an increase of 1–1.9 was considered a partial relapse. If the initial decrease in HbA_{1C} was at least 3.0, a subsequent increase of at least 3.0 was counted as relapse, and an increase of 1–2.9 was considered a partial relapse.

The frequency of relapse was highest between 6 and 12 mo after entry and declined thereafter. In patients whose decrease in HbA_{1C} was at least 1.0 during the first 6 mo, 40% relapsed between 6 and 12 mo, 30% relapsed between 12 and 18 mo, and 20% relapsed between 18 and 24 mo after entry (Fig. 4*A*). Among patients whose decrease in HbA_{1C} was at least 2.0 during the first 6 mo, 40% relapsed during the second 6 mo, but only 2% relapsed back to preentry levels during the third and fourth 6-mo periods (Fig. 4*B*). In patients whose decrease in HbA_{1C} was at least 3.0 during the first 6 mo, 20% relapsed during the second 6 mo, but only 2% increased by this degree during the third and fourth 6-mo periods (Fig. 4*C*).

In the patients with the greater degree of initial improvement, partial relapses were much more frequent than major relapses back to preentry levels (Fig. 4*B* and *C*).

The frequency of relapse was higher in women (Fig. 5). If the initial decrease in HbA_{1C} was at least 1.0, 9 of 19 (47%) of the female patients relapsed between 6 and 12 mo, compared with only 3 of 21 (14%) of the male patients (χ^2 (1), $P = 0.02$). In the group whose initial decrease in HbA_{1C} was at least 2.0, 6 of 8 (75%) of the females relapsed between 6 and 12 months, compared with only 1 of 11 (9%) of the male patients (χ^2 (1), $P = 0.003$).

CONCLUSIONS— A plan for continuing care is an essential feature in the management of every patient with diabetes. Recently published standards for medical care of patients with diabetes mellitus recommend that regular visits should be scheduled for insulin-treated patients at least quarterly and for other patients at least semiannually (15).

Dropout from follow-up was the largest potentially correctable problem in this population of patients. Various con-

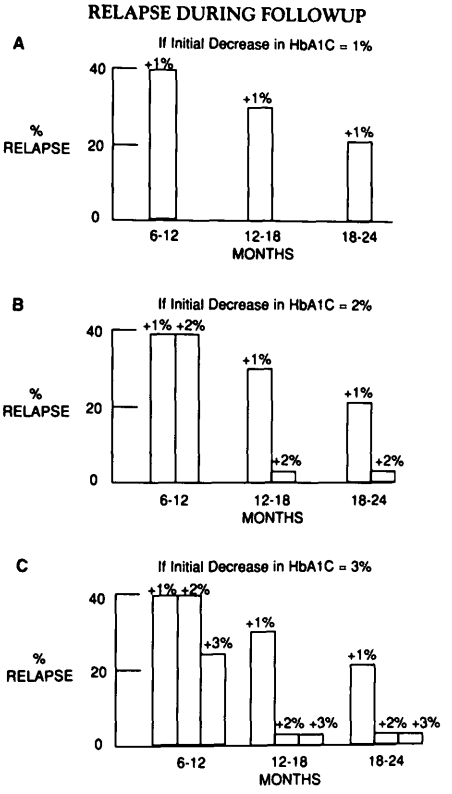

Figure 4—*A: Patients in whom HbA_{1C} decreased at least 1.0 during the first 6 mo had 40% rate of relapse to the preentry level between 6 and 12 mo (left); among those who did not relapse between 6 and 12 mo, 30% relapsed between 12 and 18 mo (middle); among those who did not relapse by 18 mo, 20% relapsed between 18 and 24 mo (right). Therefore the rate of relapse declined with the passage of time. B: Patients in whom HbA_{1C} decreased at least 2.0 during first 6 mo had 40% relapse to preentry level between 6 and 12 mo (left); only 2% relapsed to preentry levels between 12 and 18 mo, but 30% had partial relapse of 1–1.9 (middle); only 2% relapsed to preentry levels between 18 and 24 mo, but 20% had partial relapse (right). C: Patients in whom HbA_{1C} decreased at least 3.0 during first 6 mo had 20% relapse rate to preentry level between 6 and 12 mo, but 40% showed partial relapse of 1–2.9 (left); only 2% relapsed to preentry levels between 12 and 18 mo (middle) and between 18 and 24 mo (right), but 30% had partial relapse of 1–2.9 between 12 and 18 mo (middle), and 20% had similar partial relapse between 18 and 24 mo (right). Therefore, in patients with greater initial decline in HbA_{1C} (lower two panels), partial relapses were more frequent than total relapses.*

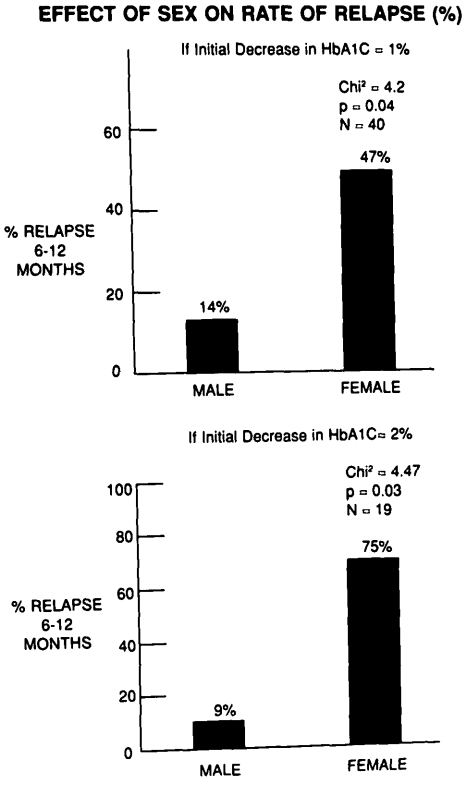

Figure 5—*The rate of relapse was higher in females than males.*

tributing factors have been considered, not all of which can be measured statistically.

Patients were less likely to return for follow-up if they lived far from the clinic, particularly if their home was >100 miles away. Therefore, ongoing care of a chronic medical condition such as diabetes should take place within a radius of 100 miles of the patient's residence.

Between 25 and 35% of all patients with diabetes mellitus use insulin (16). Patients who were receiving insulin treatment were more likely to remain in follow-up than those whose treatment consisted of oral hypoglycemic medications or diet alone. Although patients with type II diabetes who are not receiving insulin treatment might have lower motivation for follow-up care than insulin-using patients, they have greater than normal risk for development of cardiovascular disease, and many require treatment for lipid disorders or hypertension (17–19). Strategies that emphasize attention to these factors, rather than just hyperglycemia, must be developed for such patients.

Cigarette smokers dropped out from follow-up at rates almost double that of nonsmokers. Because this health-care team strongly emphasized the importance of discontinuing cigarette smoking, some of these patients may have felt that they would be rejected by the professionals if they continued to smoke (20).

Among patients in whom relapse was documented between 6 and 12 mo after entry, dropout rate after 12 mo was quite high (82%). This suggests that discouragement related to negative outcome could have influenced the tendency to drop out in this important subgroup of patients. Additionally, it is possible that interpersonal factors in the physician-patient, nurse-patient, or dietitian-patient relationships contributed to the dropout rate. Finally, financial considerations or the lack of health insurance reimbursement for outpatient diabetes care may have influenced some patients to drop out or seek alternative care. These factors were not addressed systematically during this study.

The magnitude and effects of dropout from chronic diabetes care rarely have been analyzed. At least two studies have demonstrated that patients who had frequent contact with a diabetes clinic had better glycemic control than those who did not (21,22). Hammersley et al. (23) found that defaulters from a diabetic clinic received minimal supervision and suffered greater morbidity than regular attendees. Studies of 1203 patients at a diabetes clinic at Mt. Sinai Hospital showed that 27% dropped out during the first year, followed by 16 and 17% during the next 2 yr. Those who lapsed from follow-up lived farther away, and factors related to economics and health insurance probably influenced their shift to other providers (24).

The probability of dropping out of a weight-loss program for patients with type II diabetes was significantly associated with weight gain at the last follow-up visit (25). Subjects remained in treatment if they were feeling well and were experiencing positive outcomes. When they experienced less positive outcomes, they were more vulnerable to dropout.

Dropout is not confined to patients with diabetes. Out of 1346 patients attending a hypertension clinic in Paris, 15.5% dropped out during the first year (26). A study of dropouts from the Lipid Research Clinic Coronary Primary Prevention Trial demonstrated that a computer-based surveillance system to identify delinquent patients before they became dropouts, coupled with a specific program to recover these potential dropouts, could be highly effective (27).

In summary, many factors may influence the dropout rate, including the characteristics and attitudes of the patients, the site and characteristics of the health-care providers, and the interaction between the two.

In patients who continued in follow-up, metabolic control was characterized by either maintenance or relapse. Maintenance was defined as an initial decrease from the entry level of HbA_{1C}, which continued over the duration of the followup period. In contrast, relapse was defined as an initial decrease from the entry level of HbA_{1C} followed by a subsequent tendency for the HbA_{1C} to increase toward the entry level. These definitions are difficult to quantify. For example, how much initial decrease in HbA_{1C} is considered significant improvement? How much subsequent increase in HbA_{1C} is considered a relapse? How much time can pass after the initial decrease in HbA_{1C} for the subsequent increase to be considered a relapse?

Using the criteria for improvement and relapse defined in RESULTS, we found that the rate of relapse was 20–

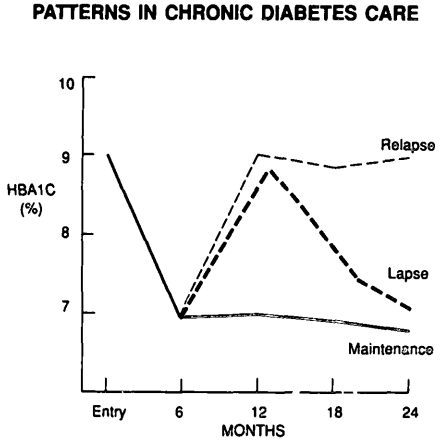

Figure 6—*Maintenance of control consists of an initial improvement in HbA_{1C} that continues during the follow-up period. Relapse consists of initial decrease followed by subsequent increase to pretreatment level. However, a temporary lapse may be followed by subsequent improvement.*

40% between 6 and 12 mo after entry. The frequency of relapse was highest at this period and declined thereafter. In the patients with greater initial improvement in HbA_{1C}, partial relapses were more frequent than total relapses. Women had a significantly higher rate of relapse than men, regardless of the degree of initial improvement in HbA_{1C}.

British workers have shown similar results. Forty-six patients, previously poorly controlled, were treated with twice-daily insulin injections, outpatient visits every 2 wk, and an intensive education program (8). The GHb concentration showed rapid improvement in the first few weeks, reaching a nadir at the 18th wk, but thereafter the values rose and were not significantly different from baseline by the 24th wk. The authors attributed the short-term improvement to an initial enthusiasm of the patients and cited the difficulty in maintaining enthusiasm over prolonged periods.

This study did not distinguish between a permanent relapse in HbA_{1C} and a temporary lapse, followed by subsequent improvement (Fig. 6). The factors that determine whether a lapse will become a permanent relapse are under study. Strategies for clinical care of patients with diabetes must acknowledge that lapses will occur and must seek ways to prevent permanent relapse.

Relapse has seldom been studied in the clinical setting of diabetes mellitus or other chronic medical disorders, but relapse prevention has been the focus of intensive studies concerned with addictive behaviors (28). Based on studies concerned with alcohol addiction, Marlatt and Gordon (28) have developed a relapse prevention model. During the time a patient maintains control, he experiences a sense of perceived ability to cope. This continues until he encounters a high-risk situation, such as a negative emotional state, interpersonal conflict, or social pressure. The patient must learn precise skills and strategies to prevent relapse at these times. They must be anticipated and practiced as one would practice a fire drill (28). The etiology and processes of the behavior changes that resulted in initial improvement may be governed by different factors than long-term maintenance (29). The relapse prevention model derived from studies of addictive behavior may provide valuable guidelines for further studies of the factors governing relapse in diabetes.

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