POPULATIONS AT RISK

Diabetes Control Improved When Inner-city Patients Received Graphic Feedback About Glycosylated Hemoglobin Levels

Rebecca B. Chapin, MD, PhD, Derrick C. Williams, MD, Richard F. Adair, MD

OBJECTIVE: To develop and test an inexpensive visual tool to help patients with diabetes improve glycemic control.

METHODS: A multidisciplinary team developed a 1-page form, the "Take-home Diabetes Record" (THDR), providing feedback to patients by displaying percent glycosylated hemoglobin (GHb) values graphically over time, with target levels highlighted. Patients with type 2 diabetes in an inner-city clinic were randomized to THDR use ($n = 57$) or not ($n = 70$) over 15 months. Self-care activities were discussed, linked with GHb results, and charted at each clinic visit. Initial and final GHb were compared.

RESULTS: Mean GHb fell significantly in THDR patients (-0.94 , $P = .003$), but not in control patients (-0.18 , $P = .36$). Mean GHb decrease was greater in THDR patients ($P = .047$). A greater proportion of THDR patients (51%) than control patients (18%) achieved a decrease in GHb ≥ 0.9 ($P = .001$).

CONCLUSIONS: A graph linking GHb and self-care activities shows promise for improving glycemic control.

KEY WORDS: diabetes; feedback; patient education; graph; urban population.

J GEN INTERN MED 2003;18:120-124.

Improving care for inner-city patients with chronic diseases is a challenge. Obstacles include poverty,¹ lack of insurance,² rising drug costs,³ failed appointments,⁴ attending multiple clinics,⁵ substance abuse,⁶ psychiatric illness,^{7,8} and budgetary pressures on providers.⁹ Effective communication between physician and patient may be limited by language barriers related to high immigration rates,¹⁰ illiteracy,^{11,12} or cultural differences.¹³ These problems are not unique to urban areas, but often are concentrated there.

Diabetes, in particular, is a disease where good communication is important. Outcomes improve when patients understand their treatment,¹⁴ receive immediate feedback,¹⁵ or report that their physicians are collaborative rather than directive.¹⁴ Outcomes also improve when

professional interpreters are available,¹⁶ and with the use of frequent computerized reminders¹⁷ or intensive nursing management.¹⁸

We hypothesized that visual, nonverbal communication could be helpful in this setting. Despite calls for behavioral research in diabetes,¹⁹ a MEDLINE (Ovid) search from 1966 to 2002 (keywords: diabetes, feedback, patient education, communication, graph, urban population) revealed only 1 letter briefly describing visual communication with diabetic patients,²⁰ and 3 reports of trials with other groups of patients.²¹⁻²³

This report describes the design and testing, in a randomized controlled trial, of a communication tool to improve diabetes care in a primary care clinic in an inner-city neighborhood in Minneapolis, Minnesota. The central idea was to communicate visually rather than verbally, using a graph of glycosylated hemoglobin (GHb) at every visit.

METHODS

Designing the Take-home Diabetes Record

At a series of meetings, input for the design of a patient-physician communication form was obtained from nurses, resident and staff physicians, social workers, diabetes educators, and a health psychologist. A name was chosen, the "Take-home Diabetes Record" (THDR) (Fig. 1). Goals thought likely to be frustrating, embarrassing, or difficult were omitted. Rather, achievable patient-specific actions were emphasized ("I took my medication correctly," "I measured my glucose daily," "I was active 3 times a week"). These were separated on the form from physician-specific measurements (GHb), but located in the same column for each clinic visit, to emphasize the connection between behavior and results. Light green shading was used for borderline GHb readings and green (a color associated with safety) for acceptable readings. Light cardboard was used for durability. The cost was 17 cents per copy.

Patients, Physicians, Study Design

The study group consisted of all patients with type 2 diabetes in an internal medicine residents' continuity clinic who had at least 1 GHb measurement during 1998, and all 30 resident physicians working in this clinic. All patients consented to use of laboratory data in a clinical research

Received from the Department of Medical Education, Abbott Northwestern Hospital, Minneapolis, Minn.

Address correspondence and requests for reprints to Dr. Adair: Abbott Northwestern Hospital # 11135, Department of Medical Education, 800 East 28th St., Minneapolis, MN 55407-3799 (e-mail: adair001@tc.umn.edu).

TAKE HOME DIABETES RECORD

Medical research shows that keeping your blood sugar close to normal can lead to a healthier future for you, your eyes, kidneys, and blood vessels. This report will guide you in doing your part, and help you and your doctor work together as a team.

NAME:

What I'm Doing:	Date:	Date:	Date:	Date:	Date:
Diabetes medication:					
"I took correctly"					
Home glucose tests:					
"I tested daily & brought to clinic"					
Exercise:					
"I was active 3 times a week"					
Eye exam (date:):					
"I had one in the last year"					
Other (BP, diet, foot care, etc):					
What My Doctor Measures:					
Ave. blood sugar	Hgb A1c				
300	12				
270	11				
Too High					
240	10				
210	9				
Better					
180	8				
150	7				
Good!					
120	6				

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FIGURE 1. The Take-home Diabetes Record as used in the study.

study. Because of concerns about the Hawthorne effect (changes in residents' behavior because they knew they were being studied), the randomization process was designed to limit how often an individual resident physician would care for patients in both the study group and the control group. Residents see all patients in this clinic, and each patient is assigned a primary resident whose name appears on the computer screen when an appointment is made. Patients see their primary resident 82% of the time. Patients were randomized by the first letter of the last name of their primary resident. For instance patients of Drs. Able and Charlie would be assigned to intervention and patients of Drs. Baker and Delta to usual care. This had the effect of randomizing patient-physician pairs, even though Dr. Able would see a few patients without the THDR in the chart, and Dr. Baker would see a few with the THDR.

The only intervention was unobtrusively placing the THDR, with brief written instructions for use, into the charts of randomized patients during the first week of January, where physicians would find them at the next clinic visit. The original cardboard THDR was kept in the clinic chart and updated at each visit. A copy was then made and given to the patient to take home, where family members could provide explanation, translation, or encouragement in the self-care activities.

No other intentional changes were made in diabetes treatment. When a third-year resident graduated in June 1999, his/her practice was assigned to an incoming intern, so patients and doctors did not move between control and intervention groups. Initial GHb was defined as the last one recorded in 1998. Final GHb was the last one recorded before March 2000. The endpoint was change in GHb.

Both the intervention and the end point measured were patient-specific.

Assessment of Diabetes

Glycosylated hemoglobin was measured on whole blood using cation exchange high-performance liquid chromatography in the Abbott Northwestern Hospital laboratory (Bio-Rad Variant analyzer, Bio-Rad Laboratories, Hercules, Calif).²⁴ Normal values were 4.0% to 6.0%. Because GHb reflects an average glucose concentration over approximately 3 months, final GHb readings were accepted only if dated at least 3 months after initial GHb, or at least 3 months after first use of the THDR in patients assigned to use. Clinic charts as well as the hospital laboratory's electronic database were searched for initial and final GHb values meeting the above criteria.

Statistical Analyses

Analysis was by intention to treat and included all randomized patients with initial and final GHb pairs. Because the GHb data were not normally distributed,

nonparametric tests were used to compare changes in GHb within intervention and control groups (Wilcoxon Signed Rank) and between groups (Mann-Whitney).²⁵ Fisher's exact test was used to compare the number of patients in the control and intervention groups who achieved a decrease in GHb ≥ 0.9 .

To look for bias introduced by unequal characteristics of patients dropping out from the 2 groups, initial GHb and demographic characteristics were compared for these patients. To look for individual variations in resident practice that could affect the results, mean change in GHb was calculated for each resident's group of patients. Mean change in GHb was compared in patients using the THDR briefly (1 to 3 values plotted) or more extensively. The possible confounding effect of a higher initial GHb occurring by chance in the intervention patients was evaluated using an analysis of covariants calculation.

RESULTS

Table 1 shows demographic and clinical characteristics of the randomized patients. There were no statistically

Table 1. Clinical and Demographic Characteristics of the Randomized Patients

Patient Characteristic	Control (N = 70)	Intervention (N = 57)	Control-Intervention Difference P Value*	Dropped Out (N = 37)
Age, y				
Geometric mean	51	54	.87	52
Range	20 to 91	32 to 83		29 to 78
Gender, n (%)			>.99	
Female	37 (53)	31 (54)		22 (59)
Male	33 (47)	26 (46)		15 (41)
Treatment modality, n (%)			.44	
Non-insulin-based therapy	51 (73)	37 (65)		25 (66)
Insulin-containing therapy	19 (27)	20 (35)		12 (32)
Entry GHb, %				
Geometric mean	8.2	8.7	.16	8.4
Range	5.4 to 13.0	5.0 to 14.0		5.9 to 13.5
Diabetes educator visits, 1998, n (%)			.35	
No visits	50 (71)	46 (81)		
1-5	20 (29)	11 (19)		
Comorbid conditions†, n (%)			>.99	
Major psychiatric diagnoses	19 (33)	17 (39)		7 (29)
Alcoholism	6 (10)	6 (14)		3 (13)
Insurance, n (%)			.32	
Medicare/Medicaid	41 (59)	34 (60)		22 (59)
None	21 (30)	12 (21)		7 (19)
Private	8 (11)	11 (19)		8 (22)
Ethnic background, n (%)			.60	
European American	27 (39)	23 (40)		10 (27)
African American	20 (29)	20 (35)		15 (41)
Recent immigrant	15 (21)	7 (12)		8 (22)
Native American	4 (6)	2 (4)		1 (3)
Other/unknown	4 (6)	5 (9)		3 (8)

* P values for group comparisons of continuous data (age, entry GHb) result from nonparametric analysis (Mann-Whitney); of categorical data in 2 × 2 format (gender, treatment modality, visits, comorbid conditions) from Fisher's exact test; and of categorical data with multiple variables (insurance, ethnic background) from χ^2 analysis.

† Variable n due to unavailable clinic charts: control (n = 58), intervention (n = 43), dropped out (n = 24).

GHb, glycosylated hemoglobin.

significant differences between groups. The immigrant patients were from Somalia, Ethiopia, Mexico, Egypt, Liberia, Laos, Togo, Russia, Tibet, Vietnam, and the Philippines.

Of the 127 patients randomized, 37 did not have a usable GHb pair, because no final GHb was drawn during the 15-month study period ($n = 34$) or the final GHb was drawn within 3 months of the initial GHb or first use of the THDR ($n = 3$). These patients were evenly divided between the intervention ($n = 18$) and control ($n = 19$) groups. Chart examination showed that the THDR had never been used in 12 intervention patients, but to avoid selection bias, these patients were included in the intention-to-treat analysis.

Analysis of the 90 patients with a usable GHb pair showed that control patients had an initial GHb of 8.1 (geometric mean), and a drop of 0.18 during the study ($P = .36$). Patients assigned to THDR use had an initial GHb of 8.8 (geometric mean), and a drop of 0.94 during the study ($P = .003$). Comparing the 2 groups, the decrease in GHb in patients assigned to THDR use was significantly larger than in controls ($P = .047$). Fifty-one percent of patients randomized to THDR use achieved a decrease in GHb ≥ 0.9 , compared with 18% of control patients ($P = .001$).

Patients who dropped out from the control group were similar to those who dropped out from the intervention group with respect to mean age (51, 53 years), initial GHb (8.6, 8.7), and immigrant status (26%, 17%); patients who dropped out were similar to patients in the randomized groups (Table 1).

Mean GHb change was plotted for the group of patients assigned to each resident. This produced a nearly normal distribution (mean, -0.25 ; median, -0.05 ; interquartile range, -1.1 to 1.0) with minimal skewness or kurtosis caused by resident outliers.

Mean change in GHb was greater in patients who used the THDR 4 or more times (-1.6) than in those who used it 1 to 3 times (-1.1), a nonsignificant difference.

By chance, the initial mean GHb in patients randomized to THDR use was higher than in controls (Table 1). The separate effect of these 2 variables (initial GHb and THDR use) was assessed by covariant analysis for the control patients and the patients who actually used the THDR. The influence of THDR use on change in GHb was significant ($P = .02$) independent of initial GHb.

DISCUSSION

The patients and physicians in this study achieved lower GHb values over 15 months when they used a visual communication tool—a graph—directed toward a simple goal. The magnitude of GHb improvement was similar to that associated with improved long-range outcomes in the United Kingdom Prospective Diabetes Study (0.9%), which studied a wider demographic cross-section of a fully insured British population.²⁶ More than half the patients who used the THDR achieved a drop in GHb $\geq 0.9\%$, compared with 18% of usual care patients. This improve-

ment was achieved at minimal cost, and in the presence of many of the barriers encountered in providing health care in urban America.²⁷

Design of the THDR was guided by reports calling for behavioral science research in treatment of chronic diseases,¹⁹ awareness of cultural differences in communication style and the role of the family,²⁸ and a model of care emphasizing an alliance between patient and provider, in contrast to simply asking for patient compliance with physician directives.²⁹ The THDR allowed patients to choose a visual goal (moving the plotted GHb dot into the green zone), and learn specific small steps they could take to accomplish it. There was regular opportunity for discussion and learning at each clinic visit, and for new behavior to be rewarded.

We recognize several limitations of this study. We did not determine whether using the THDR changed patient behavior, resident physician behavior, or both, and we did not investigate the extent of family input. Patients were exposed to the THDR for varying lengths of time; while there was a trend toward larger declines in GHb with more use of the THDR, a longer and larger study would provide more definitive data.

Twenty-seven percent of the randomized patients had no GHb recorded during the study, most lost to clinic follow-up. Although this is a high rate from a statistical standpoint, it is not a high rate of patient loss at 15 months in an inner-city clinic. It seems unlikely that losing these patients affected the results, because those who dropped out of the treatment group and out of the control group were similar with respect to age, immigrant status, and initial GHb.

The randomization process helped protect the integrity of usual care and avoid the Hawthorne effect (GHb was stable in the control group), but raises the possibility that a few individual residents who were unusually effective (or ineffective) could unduly influence the results. However, an analysis of GHb change in the group of patients assigned to each resident did not indicate any unusual clustering of outcomes.

Initial GHb was by chance higher in patients randomized to treatment, raising the possibility that the larger fall in GHb in this group could be partly explained by having more room for improvement. This was addressed directly by covariant analysis, which showed a significant impact of THDR use independent of initial GHb.

These results reinforce the importance of patient education and collaboration with physicians in treating diabetes. They suggest a role for visual communication techniques, at least in patients with potential barriers to verbal communication. They also suggest that improving care does not have to be expensive; the THDR required no nursing time, and cost 17 cents per copy.

Mark Prebonich, MD, and Dan Ruppman, MD for advice in designing the THDR and the study; Varia Kirchner for data analysis; Claus Pierach, MD for manuscript suggestions; and Terry Rosborough, MD for statistical help.

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