Comprehensive Evaluation of Community-Based Diabetic Patients

Effect of feedback to patients and their physicians: a randomized controlled trial

ROLAND G. HISS, MD[1]
MARY LOU GILLARD, MS[1]
BETTY A. ARMBRUSTER, [1]
LESLIE A. MCCLURE, MS[2]

OBJECTIVE — To demonstrate improvements in diabetes care stimulated by comprehensive evaluation of community-based diabetic patients with feedback to the patients and their physicians.

RESEARCH DESIGN AND METHODS — A comprehensive evaluation of community-based diabetic patients with annotated reporting of results to both patients and their physicians (universal intervention) was followed by random assignment of 50% of patients to individual counseling (randomized intervention). In four communities, two large and two small, 55 type 1 and 376 type 2 diabetic patients were recruited, evaluated, and reassessed at 1 year. Outcome measures were HbA_{1c}, serum cholesterol, and systolic and diastolic blood pressure.

RESULTS — There were significant improvements in all outcome measures for type 2 diabetic patients randomized to individual counseling ($P = 0.03$; follow-up rate 84%) and significant improvements in all outcome measures for all high-risk type 2 patients (highest P value = 0.004; follow-up rate 85%).

CONCLUSIONS — Comprehensive evaluation of diabetic patients at the community level with annotated reporting of results to the patients and their physicians was associated with improvement of mean HbA_{1c}, cholesterol, and systolic and diastolic blood pressure, particularly in patients in high-risk status for these outcome variables. Individual counseling of 50% of patients, randomly selected, enhanced these results.

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The U.S. health care delivery system, with respect to diabetes, is supported by vast amounts of new science. The 1990s witnessed several advances in our understanding of the pathogenesis of the complications associated with long-term, uncontrolled hyperglycemia, dyslipidemia, and hypertension (1–10). However, incorporation of these advances in the care given to large numbers of patients at the community level has been slow.

The Michigan Diabetes Research and Training Center (MDRTC) has been involved with community-based diabetes care and education in large and small communities in Michigan since 1979 (11–15). A principal mission of a DRTC, as defined by the National Commission on Diabetes, is to engage in translational research (16). Translation is the two-step process of applying the positive findings of basic laboratory investigation to patients who might benefit from it. The first step, often denoted as "bench-to-bedside," usually occurs at clinical research sites under controlled conditions. The second step, a more difficult one, extends this clinical research to the broader practice community through efforts to overcome the barriers to its adoption.

In 1994, we initiated a diabetes education program for both primary care physicians and their diabetic patients that used comprehensive evaluation of individual patients as the focus of the educational effort. This was translational research: to bring new clinical information to both physicians and their patients through interaction about problems they were facing in diabetes care. The new clinical information was presented to both parties simultaneously and in a form they could immediately use. A universal intervention and a randomly assigned intervention were used. We hypothesized that the patients who received the randomized intervention would have better outcomes than those who did not.

RESEARCH DESIGN AND METHODS

Community and patient selection

We selected four Michigan communities, two large and two small, from a pool of Michigan communities that met our criteria for communities of these two sizes. The geographic boundaries of each community were defined at baseline by designating the postal zip codes. Patients were recruited with the offer to receive a free and comprehensive evaluation of their diabetes. The offer was made by a variety of local announcements. Patients were provided a toll-free number to call the project staff and make arrangements to attend a specially arranged clinic in their community where they could be examined.

From the [1]Department of Medical Education, University of Michigan Medical School, and the [2]Department of Biostatistics, University of Michigan School of Public Health, Ann Arbor, Michigan.

Address correspondence and reprint requests to Roland G. Hiss, MD, University of Michigan Medical School, Department of Medical Education, G1103 Towsley Center, Box 0201, Ann Arbor, MI 48109-0201. E-mail: redhiss@umich.edu.

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Abbreviations: DBP, diastolic blood pressure; MDRTC, Michigan Diabetes Research and Training Center; SDP, systolic blood pressure.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Patient data

The components of the evaluation of each patient included *1*) diabetes and general medical history; *2*) current diabetes program; *3*) diet history; *4*) diabetes care profile (psychosocial assessment); *5*) standardized knowledge test and educational needs assessment; *6*) height, weight, blood pressure, foot exam, and neuropathic exam; *7*) HbA_{1c}; *8*) serum C-peptide; *9*) serum creatinine; *10*) lipid profile (cholesterol, HDL and LDL cholesterol, and triglycerides); and *11*) microalbuminuria assessment.

All biochemical analyses were performed in the core laboratories of the MDRTC. Total GHb was measured by the Glyc-Affin GHb method (EG & G Wallace, Akron, OH). Conversion to HbA_{1c} was performed using the formula (total GHb × 0.6) + 1.5 (17). The lipid profile components were assayed with Roche Reagents (Roche Diagnostic Systems, Branchburg, NJ). C-peptide was measured by radioimmunoassay with ^{125}I-labeled human C-peptide (Linco Research, St. Louis, MO).

The project staff included a research associate, who collected demographic information and administered the survey instruments, and a diabetes nurse specialist, who examined the patient, drew blood, and obtained a urine specimen for transport to the core laboratories of the MDRTC.

Determination of diabetes type was based on the serum C-peptide value using Diabetes Control and Complications Trial entry criteria (18). All data were entered into a relational database with data management and analysis performed in cooperation with the Biostatistics Core of the MDRTC.

Research design

We recruited two sequential cohorts of patients in the four selected communities, with each cohort spanning 2 years. Patient recruitment and evaluation of diabetic status occurred during the first 6 months of the 2-year span; reevaluation of patients, in which all assessments were repeated, occurred during the last 6 months. As patients entered the study, they were randomly assigned, using a random number table, to one of two groups: *1*) the control group, comprised of patients who received an annotated report of their evaluation results by mail, as did their physicians; and *2*) the experimental group, comprised of patients who met with the project nurse after their baseline assessment to receive a personal report on the results of that assessment, followed by individually arranged meetings with the nurse; in addition, these patients' physicians received a copy of the annotated report by mail. The meetings between the nurse and experimental group patients focused on problems identified during the assessment and recommendations for actions by the patient to address these problems. In most instances, the patient was advised to seek the counsel of his or her primary care physician concerning the identified problems, and the physician was informed that the patient had been so advised.

The project thus had two interventions: *1*) universal intervention, in which an annotated report of a comprehensive evaluation of community-based diabetic patients was sent to the patients and their physicians, and 2) randomized intervention, for a randomly selected 50% of patients, in which individual educational and counseling sessions were held that encouraged the patients to consult their physicians about identified problems.

This project received the approval of the Institutional Review Board of the University of Michigan Medical School. Written informed consent was obtained from all patients at the time of their entry into the study.

Outcome Variables Selection

Four outcome measures were selected for analysis of pre- and postintervention status of patients: HbA_{1c}, serum cholesterol, and systolic and diastolic blood pressure (SBP and DBP, respectively). These selections were based on the widely recognized importance of these factors in the pathogenesis of micro- and macrovascular complications of diabetes. All biochemical assays were performed in the core laboratories of the MDRTC by the same methods throughout. All blood pressure determinations used a random zero sphygmomanometer.

High-risk status for each outcome measure was assigned according to the following criteria: $HbA_{1c} \geq 7.5\%$, cholesterol ≥6.22 mmol/l (≥240 mg/dl), SBP ≥140 mmHg, and DBP ≥90 mmHg.

Statistical analysis

For the four outcome variables of interest, change was defined as the value when postintervention data were collected minus the baseline value. Two-tailed two-sample *t* tests were used to compare the means of the two groups, and two-tailed paired *t* tests were used to test mean changes within each group. Because of skewness, cholesterol was analyzed after a logarithmic transformation.

In addition, an analysis was performed to determine the aggregate change in the four variables of interest. For each variable, the difference in values from baseline to postintervention data was calculated. Each difference was then ranked and rescaled to 0–1 by dividing by the highest rank plus 1. A score was determined by averaging the rescaled ranks, with SBP and DBP each weighted as 50%.

RESULTS — In all, 431 patients were recruited to the study, 229 in the first cohort, 202 in the second. The number of type 1 patients in this study (55) was small, in keeping with the relative rarity of this diagnosis at the community level. The type 1 patients participated in the study interventions, but the effectiveness of the project as a community-based translational effort was determined from experience with the type 2 population. Of the 376 type 2 patients enrolled, postintervention data were obtained on 314 (84%).

The demographic and diabetes-related clinical features at baseline for the 376 type 2 patients are listed in Table 1. Table 1 also lists the baseline data for the 198 (53%) type 2 patients meeting the criteria for high risk for HbA_{1c} (≥7.5%). The baseline demographics were similar for all four high-risk groups.

Figure 1 shows the flow of the randomized intervention for the type 2 patients. Table 2 shows the results of the four outcome measures for the 314 type 2 patients for whom postintervention data were obtained. The oral antidiabetic agents, metformin and troglitazone, became available during the study. To eliminate the potential influence of these agents as an explanation for the HbA_{1c} results, the values of patients taking either of these medications at baseline, but not after intervention, or vice versa, were not included in the HbA_{1c} calculations.

For each outcome variable, the experimental group—those randomized to individual meetings with the project nurse—showed improvement that was statistically significant, whereas the con-

Table 1—*Demographics and diabetes-related clinical features at baseline for type 2 diabetic patients and those at high risk for HbA_{1c}*

	All type 2 diabetic patients		High-risk type 2 diabetic patients	
	Control	Experimental	Control	Experimental
n (%)	190 (50.5)	186 (49.4)	110 (56)	88 (44)
Age (years)	63.6 ± 12.4	64.5 ± 12.3	63.0 ± 11.9	61.6 ± 12.6
Duration (time since diagnosis in years)	10.2 ± 0.5	9.0 ± 8.6	11.9 ± 10.0	10.4 ± 9.4
Male	73 (38)	88 (47)	42 (38)	40 (46)
Ophthalmologist ever	100 (53)	108 (58)	58 (53)	51 (58)
Ophthalmologist last 2 years	94 (50)	101 (54)	53 (49)	47 (53)
Insulin	58 (31)	64 (35)	39 (36)	42 (48)
Metformin	4 (2)	6 (3)	4 (4)	3 (3)
ACE inhibitor	18 (10)	21 (11)	8 (7)	8 (9)
Current smokers	18 (9.5)	21 (11.4)	12 (10.9)	12 (13.6)
HbA_{1c} (%)	8.0 ± 1.9	7.9 ± 1.8	9.3 ± 1.3	9.4 ± 1.4
Systolic blood pressure (mmHg)	141.4 ± 22.7	142.5 ± 22.9	145 ± 23.5	139 ± 22.6
Diastolic blood pressure (mmHg)	77.6 ± 11.6	77.2 ± 11.6	79.1 ± 11.0	78.0 ± 11.9
Cholesterol (mmol/l)	5.38 ± 1.25	5.42 ± 1.15	5.43 ± 1.30	5.66 ± 1.37
Cholesterol/HDL	5.8 ± 2.1	6.0 ± 2.1	5.9 ± 2.3	6.6 ± 2.4
Contacts with project nurse	0.5 ± 0.5*	3.3 ± 2.03	0.5 ± 0.5*	3.9 ± 2.2
Patients who declined individualized counseling	N/A	38 (20)	N/A	12 (14)
Postintervention data collection	156 (82)	158 (85)	92 (84)	75 (85)

Data are means ± SD or *n* (%). *Project nurse contacts with control patients occurred only during retinopathy screening sessions, which were offered to all patients in the study. N/A, not available.

trol group did not. When the scores on the four variables were aggregated, a *t* test showed that the experimental group had a larger aggregate change than the control group ($P = 0.03$). The nurse/patient contacts associated with the improvements in the experimental group were modest because of the great distances involved between the MDRTC and the representative target communities (100–220 miles). Table 1 notes the mean number of such contacts to be 3.3: 1.9 (range 1–7) for face-to-face meetings and 1.4 (range 1–6) for phone contact. Face-to-face meetings averaged 45 min in duration, and phone contacts averaged 20 min. Approximate costs to deliver the nurse intervention could be projected from these contact figures, which we estimate to be 4 hours of professional time per patient.

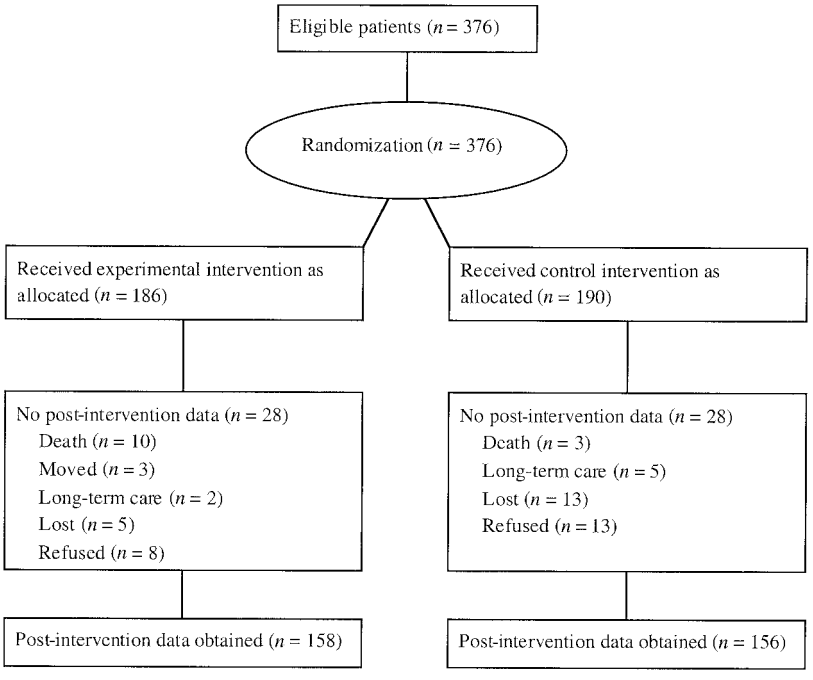

Figure 1—*Flow chart of randomized intervention for type 2 diabetic patients.*

The influence of the nurse/patient contacts was further analyzed by comparing the change in outcome variables for the type 2 experimental patients who accepted the nurse intervention ($n = 148$) to those who declined it ($n = 38$) (Table 1). Postintervention data were available for 127 (86%) of the former group and 31(81%) of the latter. The group participating in the nurse intervention had a larger mean HbA_{1c} value at baseline (7.9%; $P = 0.004$), partially explaining why they accepted the intervention, and a greater mean lowering of HbA_{1c} at postintervention follow-up (0.4%; $P = 0.03$) than the group declining the intervention. In fact, the nonintervention group showed a small mean rise of HbA_{1c} (0.2%). Similar trends were seen in the group at high risk for HbA_{1c} at baseline, only of greater magnitude. There were no differences in mean cholesterol, SBP, or DBP between the two groups.

Table 3 provides the results for patients at baseline who met criteria for high-risk status on any of the four variables of interest and from whom postinter-

Table 2—*Outcome measures of all 314 (84%) of type 2 diabetic patients with postintervention data*

	n	Baseline	Mean change	*P*
HbA_{1c} (%)				
Experimental	137	7.7 ± 0.2	−0.3 ± 0.1	0.02
Control	133	7.9 ± 0.2	−0.2 ± 0.1	0.18
Systolic blood pressure (mmHg)				
Experimental	158	143 ± 1.8	−6.3 ± 2.1	0.003
Control	155	141 ± 1.8	−1.0 ± 1.9	0.61
Diastolic blood pressure (mmHg)				
Experimental	158	77 ± 0.90	−2.4 ± 1.1	0.03
Control	154	77 ± 0.96	−1.6 ± 1.2	0.19
Cholesterol (mmol/l)				
Experimental	158	5.46 ± 0.10	−0.25 ± 0.08	0.0006
Control	157	5.39 ± 0.10	−0.06 ± 0.09	0.45

Data are means ± SEM.

vention data were obtained (238 unique patients, representing 76% of the 314 patients with postintervention data). In these high-risk cases, the effect of the universal intervention—the annotated report of the comprehensive evaluation supplied to both patient and his/her physician, alerting all parties to existing problems—was sufficient to produce gratifying changes in both the experimental and control groups.

The 376 type 2 patients were served by 208 primary care physicians. Within the defined geographic areas of the four study communities, 166 (42%) of the 391 primary care physicians with office addresses in those areas received annotated reports of the evaluation of their type 2 patients.

CONCLUSIONS — In this study, the comprehensive evaluation of community-based type 2 diabetic patients and the annotated reporting of the results of that evaluation to both the patients and their primary care physicians led to significant improvement in important outcome measures. Follow-up counseling by a diabetes nurse specialist for a random 50% of patients enhanced these results. This translational effort wove its messages into the naturally occurring educational events that affect the professional lives of physicians and the personal lives of their patients. Physicians and patients both learn from continuing experience, and, for both, the identification of a problem presents a teachable moment.

The study reached 42% of the primary care physicians with professional offices in the four defined communities, arguably a much greater outreach than would have been the experience of a traditional continuing medical education offering. For physicians with experimental group patients in their practice, the influence of the study on their diabetes care was greater than on the physicians of control group patients. The physicians of control group patients received only an annotated report in their office mail. Physicians of the experimental group patients received a similar report, but had further interaction with the study as their patients sought their advice on clinical problems identified during the nurse/patient meetings. Through these patient/nurse/physician interactions, new clinical science was incorporated into diabetes care. (It should be noted that patients were recruited to the study using a variety of local announcements and randomly assigned to experimental or control status. As a consequence, the primary care phy-

Table 3—*Outcome measures of 238 unique type 2 diabetic patients at high risk (76% of 314 patients with postintervention data)*

	*n**	Baseline	Mean change	*P*
HbA_{1c}				
Experimental	63	9.2 ± 0.17	−1.1 ± 0.2	0.0001
Control	75	9.2 ± 0.14	−0.5 ± 0.2	0.006
Systolic blood pressure (mmHg)				
Experimental	62	163 ± 2.3	−18.5 ± 3.5	0.0001
Control	54	162 ± 2.5	−17.2 ± 2.9	0.0001
Diastolic blood pressure (mmHg)				
Experimental	24	96. ± 1.6	−15 ± 2.9	0.0001
Control	24	95 ± 1.5	−17.7 ± 3.7	0.0001
Cholesterol (mmol/l)				
Experimental	33	7.23 ± 0.17	−0.90 ± 0.23	0.0003
Control	30	7.25 ± 0.25	−0.75 ± 0.25	0.004

Data are means ± SEM. *The sum of this column (365) is greater than the number of unique patients with high risk factors (238) because many patients had more than one risk factor.

sicians serving these patients [n = 208] may have had only one or more experimental patients [n = 94, 45%], one or more control patients[n = 85, 41%], or both [n = 29, 14%].)

Improvement in the four outcome variables of interest for the experimental patients was modest, but the aggregate effect was significant. The modest but statistically significant differences are explained by *1*) the modifying effect on mean change produced by including many patients who did not need improvement in the variable of interest; *2*) the observation that the experimental patients who declined the nurse intervention experienced a small worsening of their mean HbA_{1c} values, whereas those who participated in the intervention had an improvement in their mean value for this measure; and *3*) the fact that the total contact time with individual patients who participated in the nurse intervention was small (distance factor effect) and thus would be inexpensive to reproduce in real world settings.

The data collectors (nurse and research associate) were not blinded to patient assignment to experimental or control group. However, the four outcome measures on which the conclusions of this study are based were not subject to bias. The HbA_{1c} and cholesterol measures were performed in the core laboratories of the MDRTC, whose staff were blinded to patient assignment; SBP and DBP were recorded using a random zero sphygmomanometer specifically to avoid observer bias. Demographic and historical data were obtained via patient response on our standardized survey instruments.

In conclusion, we believe this study demonstrates a means to foster translation (incorporation) of new clinical science into community-based diabetes care. The study took advantage of two traditionally effective ways by which physicians and patients acquire new knowledge and skills—continuing experience punctuated by teachable moments.

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References

1. Abraira C, Colwell JA, Nuttall FQ, Sawin CT, Nagel NJ, Comstock JP, Emanuele NV, Levin SR, Henderson W, Lee HS: Veterans Affairs cooperative study on glycemic control and complications in type 2 diabetes (VA CSDM): results of the feasibility trial. *Diabetes Care* 18:1113–1123, 1995
2. Klein R, Klein BEK, Moss SE, Cruickshanks KJ: The medical management of hyperglycemia over a 10-year period in people with diabetes. *Diabetes Care* 19: 744–750, 1996
3. Laffel LMB, McGill JB, Gans DJ: The beneficial effect of angiotensin-converting enzyme inhibition with captopril on diabetic nephropathy in normotensive IDDM patients with microalbuminuria. *Am J Med* 99: 497–504, 1995
4. Stone NJ: Lipid management: current diet and drug treatment options. *Am J Med* 101:40S–49S, 1996
5. The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 329:977–986, 1993
6. The Diabetes Control and Complications Trial Research Group: The relationship of glycemic exposure (HbA_{1c}) to the risk of development and progression of retinopathy in the diabetes control and complications trial. *Diabetes* 44:968–983, 1995
7. Viberti G, Mogensen CE, Groop LC, Pauls JF: Effect of captopril on progression to clinical proteinuria in patients with insulin-dependent diabetes mellitus and microalbuminuria. *JAMA* 271:275–279, 1994
8. Laakso M: Glycemic control and the risk for coronary heart disease in patients with non-insulin-dependent diabetes mellitus. *Ann Intern Med* 124:127–130, 1996
9. U.K. Prospective Diabetes Study Group: Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352:837–853, 1998
10. U.K. Prospective Diabetes Study Group: Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes (UKPDS 38). *BMJ* 317:703–713, 1998
11. Hiss RG, Bowbeer MA, Hess GE, Stepien CJ, Armbruster BA, Eds.: *Diabetes in Communities II*. Ann Arbor, Michigan, University of Michigan, 1992
12. Anderson RM, Hess GE, Davis WK, Hiss RG: Community diabetes care in the 1980s. *Diabetes Care* 11:519–526, 1998
13. Hiss RG, Anderson RM, Hess GE, Stepien CJ, Davis W: Community diabetes care: a ten-year perspective. *Diabetes Care* 17: 1124–1134, 1994
14. Anderson RM, Hiss RG, Stepien CJ, Fitzgerald JT, Funnell MM: The diabetes education experience of randomly selected patients under the care of community physicians. *Diabetes Educ* 20:399–405, 1994
15. Hiss RG: Barriers to care in non-insulin-dependent diabetes mellitus: the Michigan experience. *Ann Intern Med* 124:146–148, 1996
16. National Institutes of Health, US Department of Health, Education and Welfare Public Health Service: *Report of the National Commission on Diabetes to the Congress of the United States. Volume I. The Long-Range Plan to Combat Diabetes*. Washington, DC, U.S. Govt. Printing Office, 1975 (NIH publ. no. 77-1018)
17. Hayward RA, Manning WG, Kaplan SH, Wagner EH, Greenfield S: Starting insulin therapy in patients with type 2 diabetes: effectiveness, complications, and resource utilization. *JAMA* 278:1663–1669, 1997
18. The Diabetes Control and Complications Trial Research Group: The diabetes control and complications trial (DCCT). *Diabetes* 35:530–545, 1986