Evaluation of a Nurse-Care Management System to Improve Outcomes in Patients With Complicated Diabetes

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OBJECTIVE — This study evaluated the efficacy of a nurse-care management system designed to improve outcomes in patients with complicated diabetes.

RESEARCH DESIGN AND METHODS — In this randomized controlled trial that took place at Kaiser Permanente Medical Center in Santa Clara, CA, 169 patients with longstanding diabetes, one or more major medical comorbid conditions, and HbA_{1c} >10% received a special intervention ($n = 84$) or usual medical care ($n = 85$) for 1 year. Patients met with a nurse-care manager to establish individual outcome goals, attended group sessions once a week for up to 4 weeks, and received telephone calls to manage medications and self-care activities. HbA_{1c}, LDL, HDL, and total cholesterol, triglycerides, fasting glucose, systolic and diastolic blood pressure, BMI, and psychosocial factors were measured at baseline and 1 year later. Annualized physician visits were determined for the year before and during the study.

RESULTS — At 1 year, the mean reductions in HbA_{1c}, total cholesterol, and LDL cholesterol were significantly greater for the intervention group compared with the usual care group. Significantly more patients in the intervention group met the goals for HbA_{1c} (<7.5%) than patients in usual care (42.6 vs. 24.6%, $P < 0.03$, χ^2). There were no significant differences in any of the psychosocial variables or in physician visits.

CONCLUSIONS — A nurse-care management program can significantly improve some medical outcomes in patients with complicated diabetes without increasing physician visits.

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In recent years, a number of strategies have been developed to improve the effectiveness and reduce the cost of managing individuals with chronic conditions. Comprehensive management of chronic illness requires addressing three interrelated domains: *1*) medical, 2) psychosocial (including mood, self-management skills, and self-care activities), and *3*) lifestyle (including exercise and diet).

Of the various chronic conditions, complicated diabetes is particularly challenging to manage. To achieve the medical goals suggested by all current guidelines, patients are required to self-monitor blood glucose, take frequent insulin injections, and/or use many other medications, in addition to attending to diet, foot and oral care, and obtaining yearly monitoring of visual and renal status. Finally, most patients would benefit from weight loss and exercise. Optimal glycemic control reduces the development and progression of microvascular and neuropathic complications by ~50% in those with type 1 and type 2 diabetes (1,2). Moreover, cardiovascular disease (CVD) is the most frequent and costly complication of type 2 diabetes (3) and requires adequate management to slow its progression.

Studies of nurse-care managers using telephone delivery interventions to provide ongoing care for patients with diabetes have shown significant reductions in HbA_{1c} and other measures of diabetes control (4–7). These studies have used a combination of face-to-face visits and telephone follow-up (4), automated telephone systems with nurse-initiated telephone contacts (5), and more generalized approaches facilitating close follow-up through primary care (6). Although some nurse-care–managed interventions have referred patients for management of coronary risk factors (7) and included some interventions to improve lifestyle and reduce risk factors, no study has evaluated the effects of a nurse-care manager providing algorithm-directed interventions for diabetes, hyperlipidemia, hypertension, and depression.

The purpose of this randomized controlled trial was to determine whether an integrated nurse-care management intervention would significantly improve medical, psychosocial, and lifestyle outcomes in patients with complicated diabetes compared with usual care.

RESEARCH DESIGN AND METHODS

Enrollment, orientation, and randomization

This study was conducted within the Kaiser Permanente Medical Center. All study procedures were approved by the human subjects committee. A computerized database was used to identify patients with an HbA_{1c} >10.0% and an ICD-9–based diagnosis of diabetes and hypertension, dyslipidemia, or CVD. Potentially eligible patients were then screened via telephone regarding their eligibility for the study. Patients were considered ineligible if they did not speak English, were not willing or able to participate in the group sessions

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Abbreviations: BDI, Beck Depression Inventory; CVD, cardiovascular disease; RN, registered nurse.

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

once a week for 4 weeks, had congestive heart failure as their primary diagnosis, were <18 years of age, were pregnant, were enrolled in a diabetes management clinic, or fell into the "other" category (e.g., living too far away/moving, deceased, or no-show to baseline appointment). All eligible patients met with a research assistant blinded to the subject's random assignment for baseline and follow-up assessments at 1 year.

Usual care

Patients randomized to usual care were instructed to remain under the treatment of their primary care physician. They received a folder containing a copy of the informed consent, diabetes pamphlets, a Medic Alert pamphlet, and a half-sheet of instructions encouraging them to maintain contact with their personal physician and to attend general diabetes education classes at their medical center. Participants were told that at the end of 1 year they would receive a workbook and have an opportunity to meet one-on-one or attend a group class with a nurse-care manager.

Intervention

Initial individual meeting with an registered nurse. A 90-min consultation was scheduled to allow the registered nurse (RN) to review the patient's medical, lifestyle, and psychosocial status. The RN performed a foot exam and checked and recorded blood pressure and pulse. An initial self-management plan was developed.

Group class. All intervention patients were asked to attend a 1- to 2-h group class (4–10 participants per group) that met once a week for 4 weeks. Each group, designed to follow a workbook specifically created for the program, included some didactic material, although the focus was on group discussion, participation, and problem-solving.

Telephone follow-up calls. The telephone call was structured to first review the patient's goals, followed by medication use, symptoms, glucose monitoring, blood pressure monitoring (if appropriate), and self-management/care activities. Patients with a Beck Depression Inventory (BDI) score >10 were reassessed and evaluated and/or referred for psychopharmacology/therapy as needed. Patients with alcohol problems were also monitored and referred. All participants received an initial telephone call from a program nurse-care manager before the fourth group session. Subsequent calls were scheduled for 5, 8, 12, 16, 20, 28, 36, and 44 weeks into the program and were designed to average 15 min. Additional calls were provided to participants as needed.

Algorithms. The nurse-care managers used treatment algorithms developed by the Kaiser Permanente Medical panels based on national guidelines (8) to titrate the patients' medications for diabetes, cholesterol, and hypertension. (The guideline for HbA_{1c} was <7.5% and has since been reduced to <7.0%.) The patient's primary care physician was called if a new medication was indicated or to report any unusual findings.

The nurse-care managers, selected for having extensive experience in managing lipids and hypertension, underwent several days of training on the Kaiser Permanente protocols for diabetes and cholesterol. For hypertension and depression, nurse-care managers attended diabetes group classes and shadowed some of the diabetes care managers and physicians treating patients with diabetes before beginning the project. (A list of the core competencies for the diabetes nurse-care managers is available from the authors.)

Measures

Consistent with recent recommendations, a number of dimensions of diabetes care were measured (9). At the baseline visit and 1 year later, patients completed self-report forms, laboratory tests were obtained, and blood pressure, weight, and height were measured. Physician satisfaction forms were sent out after the study was completed. The nurse-care managers maintained records of all patient contacts and activities related to the intervention.

Diagnosis. Patients were considered diabetic if they had a fasting blood glucose >125 mg/dl (7.1 mmol/l) and/or symptoms of diabetes and a nonfasting glucose >200 mg/dl (11.2 mmol/l). The total number of diagnoses indicating serious conditions (those requiring medical treatment and likely to lead to disability and/or death) were determined from the computerized record.

Medical. HbA_{1c} (%), total LDL and HDL cholesterol, triglycerides, glucose, and urinalysis (for microalbumin) were measured using standard measures at the Kaiser Permanente regional laboratories. Blood pressure was obtained using a standardized mercury sphygmomanometer and protocol. At baseline and follow-up, all subjects were asked if they had had a dilated eye exam, flu shot, or foot or dental exam in the last year. Patients were asked if they smoked cigarettes or used any tobacco products and, if so, the type and amount.

Psychosocial. The Duke Activity Status Index (10) and the Short Form-36 health survey questionnaire were used to assess patients' quality of life (11). The BDI was used to measure depression; scores >10 have been shown to be indicative of depression in patients with diabetes (12).

Patient and physician satisfaction. At follow-up, intervention patients completed a written survey assessing their satisfaction with the program. Physicians who had two or more of their patients enrolled in the program were asked to complete a written survey assessing satisfaction with the program.

Medical utilization. Patient computerized records were reviewed for the number of physician visits that occurred during the period of observation (some patients were not enrolled in the health care system for the entire time).

Statistical analysis

The groups were compared for baseline differences using *t* tests and χ^2 as appropriate. An ANCOVA was used to compare change scores between groups, with baseline values used as a covariate. Cohen-effect sizes were computed on the difference in the means between intervention and usual care using the pooled baseline SD.

RESULTS

— From 17 May 1999 to 30 May 2000, 748 patients were identified through the computerized database and were approved for contact by their physicians. Of these, 17 refused further contact and 231 could not be reached or did not return telephone calls. Of the remaining 500 patients, 159 were not eligible, leaving 341 patients who were eligible for participation in the study. The reasons for ineligibility were language barrier (n = 53), enrolled in diabetes management program (n = 19), medical problems restricting participation (e.g., immobile or severe chronic heart failure [n = 38]), and unavailable for group sessions (n = 33), other (n = 16). Of the eligible patients,

Table 1—*Patient demographic and medical characteristics*

Characteristic	Usual care	Intervention
n	85	84
Age (years)	54.8 ± 11.4	55.5 ± 8.9
Male	55.3	50.0
Education		
High school graduate or less	21.2	26.2
Attended some college	37.6	42.9
College graduate	21.2	19.0
Postgraduate degree	20.0	11.9
Ethnicity		
Caucasian	56.5	66.7
African American	9.4	6.0
Asian	9.4	10.0
Hispanic	21.2	14.3
East Indian	2.4	1.2
Other	1.2	—
Type 2 diabetes	97.0	93.0
Hypertensive	65.9	65.5
Hypercholesterolemic	37.6	39.3
CAD/CVD	21.2	25.0
Depression	9.4	13.1
Serious comorbid conditions	4.2 ± 2.7	4.9 ± 2.8

Data are means ± SD. CAD, coronary artery disease.

169 (59%) agreed to participate and were randomized to usual care ($n = 85$) or the nurse-managed intervention ($n = 84$).

The demographics of the 169 patients enrolled in the study can be seen in Table 1. There were no differences between usual care and intervention subjects for any of these variables. During the course of the study, 14 patients in usual care and 17 patients in the intervention dropped out of the study or were lost to follow-up. There was one death in usual care and two deaths in the intervention group. The mean HbA_{1c} levels had declined slightly between the time that the patients were identified via the computer and the time that they underwent the baseline analysis (Table 2).

Medical outcomes

At 1 year, the mean changes in HbA_{1c} and total and LDL cholesterol were significantly greater for the intervention group than for the usual care group (Table 2). These differences remained significant when analyzed based on intention to treat. In addition, significantly more patients in the intervention group met the goals for HbA_{1c} (42.6%) than patients in usual care (24.6%, $P < 0.03$, χ^2) (Table 3). At baseline, only 7% of usual care and 8% of intervention patients were smoking, leaving little room for change.

Self-care and psychosocial outcomes

At 1 year, there were no significant differences between the groups for any of the self-care or psychosocial variables. In general, scores on these variables were high and remained so for both groups (Table 3). Patients also reported high levels of confidence to engage in the behaviors necessary to manage their diabetes; the intervention group's mean level of confidence increased from 65 to 76%, while the control group's increased from 58 to 72%. There was a significant improvement in the mood for both groups.

Patient attitudes

At follow-up, 57 of 61 patients completed a satisfaction survey. Of the patients completing a post satisfaction assessment, 90% stated the program was moderately ($n = 19$) to extremely ($n = 32$) helpful. Ninety-two percent of patients also said that the program was moderately to extremely helpful in preparing them to self-manage their conditions. Patients attended, on average, 3.5 of the 4 group classes.

Physician attitudes

Of 15 physicians caring for two or more intervention patients, 13 returned the physician satisfaction questionnaire. Of these 13 physicians, 9 strongly recommended that the program be adopted by their health care system. Nine physicians felt that the program decreased the time they spent with patients; four felt that it increased the time.

Table 2—*Baseline medical values for patients present at 1 year*

	Usual care ($n = 66$)		Intervention ($n = 61$)		
Characteristic	Before	Change	Before	Change	Effect size
HbA_{1c} (%)	9.5 ± 0.3	−0.35	9.5 ± 0.3	−1.14*	0.37
Total cholesterol (mg/dl)	224.1 ± 6.7	−11.5	210.4 ± 6.0	−20.6*	0.18
LDL cholesterol (mg/dl)	123.9 ± 4.7	−6.5	124.1 ± 5.2	−19.4†	0.33
HDL cholesterol (mg/dl)	46.8 ± 1.5	−0.7	48.0 ± 1.6	0.2	0.07
Triglycerides (mg/dl)	243.8 ± 18.2	−10.5	195.2 ± 12.8	−11.0	0
Glucose (fasting) (mg/dl)	196.9 ± 8.6	−13.4	197.6 ± 10.8	−25.0	0.16
Systolic blood pressure (mmHg)	128.5 ± 2.4	8.6	126.5 ± 1.9	4.4	0.28
Diastolic blood pressure (mmHg)	72.3 ± 1.5	1.9	73.3 ± 1.4	2.2	0.03
BMI (kg/m^2)	32.8 ± 0.9	−0.3	34.6 ± 1.1	0.5	0.11

Data are means ± SD. To convert glucose values to mmol/l, multiply by 0.05551. To convert HDL and LDL cholesterol to mmol/l, multiply by 0.02586. To convert triglyceride values to mmol/l, multiply by 0.01129. *$P = 0.01$; †$P = 0.02$.

Table 3—*Percent of patients meeting outcome goals at 12 months*

Variable	Goal	Usual Care (n = 66)		Intervention (n = 61)		P
		Before	After	Before	After	
HbA_{1c}	<7.5	—	24.6	—	42.6	<0.03
Total cholesterol (mg/dl)	≤200	42.2	51.6	44.3	67.2	>0.2
LDL cholesterol (mg/dl)	≤100	27.1	37.3	33.9	45.2	>0.2
HDL cholesterol (mg/dl)	≥35	90.3	91.9	90.3	88.7	>0.2
Glucose (fasting) (mg/dl)	≤110	10	5	17.5	15.8	0.07
BMI (kg/m^2)	<30	33.3	38.6	37.7	30.2	>0.2
Systolic blood pressure (mmHg)	≤130	57.6	42.4	68.9	52.5	0.06
Diastolic blood pressure (mmHg)	≤85	86.4	84.7	90.2	83.6	>0.2
Foot exam (%)	1	65.5	72.4	42.9	73.2	0.2
Dilated eye exam (%)	1	71.9	67.2	71.2	79.7	0.1
Flu shot (%)	1	68.8	67.2	67.2	72.1	>0.2
Dental exam (%)	1	82.8	84.5	81.8	70.9	>0.2
Pneumovax shot (%)	1	54.1	57.4	51.7	63.8	≥0.2

Utilization

There was no significant change in the number of physician or emergency room visits or days of hospitalization for the year preceding and the year of the intervention, and there were no significant differences in utilization seen between intervention and usual care patients. In the intervention group, mean physician's visits were 5.7 (range 1–51) for the year before the study and 5.3 (0–37) during the study. In the usual care group, these numbers were 4.5 (0–12) in the year before the study and 4.9 (0–19) during the study. There were no significant changes in hospitalization days or emergency room visits.

Intervention effort

For patients completing 1 year of intervention (n = 61), the mean number of phone contacts was 12.8 (range 3–30). The nurse-care managers ordered an average of 5.2 (1–12) lab updates. They made an average of 3.1 (1–8) phone contacts with the doctor and very few referrals (0.2 [0–2]). The mean change in diabetes medication was 5.2 ± 4.4. These changes most often related to titration of medications. On average, patients were started on one additional lipid medication during the course of the study period. Overall, 21 patients were on cholesterol medications at baseline compared with 38 at follow-up. Few changes occurred with hypertension medications; most patients who needed them were on ACE inhibitors. In the intervention group, five patients were started on antidepressant medication. Two patients were referred for treatment for alcohol dependence (comparable data are not available for usual care).

CONCLUSIONS — This study demonstrated that a nurse-care management program for patients with complicated diabetes and other chronic conditions significantly improved HbA_{1c} levels and total and LDL cholesterol. The program was well received by patients and physicians and resulted in no increase in physician visits. There were no significant changes in the psychosocial variables, as both groups at baseline reported high levels of functioning and confidence to engage in behaviors necessary to manage their illness and self-care activities. To our knowledge, this is one of the first trials of nurse-care management that has attempted to manage not only multiple chronic conditions, but lifestyle and psychosocial aspects of the patient's care as well.

The fact that 43% of these patients were able to achieve an HbA_{1c} ≤7.5% is impressive, particularly because patients were selected on the basis of lack of control. The results compare favorably with other studies using nurse-care management. Weinberger et al. (6) found significant but small differences in HbA_{1c} and fasting blood glucose by using nurses to contact patients by telephone at least monthly to provide information, reinforce compliance with regimens, monitor patients' health status, facilitate resolution of identified problems, and facilitate access to primary care. The Piette et al. (5) study found that among patients with baseline HbA_{1c} levels ≥9%, mean end point values were 9.1 and 10.2% for intervention and usual care, respectively. Aubert et al. (4) also used nurse-care managers in a randomized controlled trial. Patients in the nurse-care management group had a net decrease of 1.1% of HbA_{1c} from baseline to 1 year, compared with the net change of 0.9% over a comparable period in the usual care group. However, while the Aubert et al. (4) study showed favorable changes in HbA_{1c} and fasting glucose levels, no changes were noted in systolic or diastolic blood pressure, lipid levels, or body weight. In our study, the significant change in not only HbA_{1c}, but also improvements in both total and LDL cholesterol, reflect the capability of nurse-care managers to manage multiple conditions simultaneously. However, it is noteworthy that 25% of the control subjects achieved HbA_{1c} levels of <7.5% by the end of the study. These changes may have occurred because of more aggressive medication management by the patients' usual care and increased contact with other health care professionals.

The intervention was less intensive than that in the Aubert et al. (4) study (which provided ≥25 calls/year/patient and included family visits and 12 h of group diabetes educational classes) but similar in intensity to that in the Piette et al. (5) study (which provided, on average, 15 phone calls) and in the Weinberger et al. (6) study (which provided about 12

calls). It is likely that a program that included a more intensive exercise intervention than we provided would require more calls, however.

There are a number of practical advantages to having one individual manage multiple aspects of care for patients with chronic conditions (13). Many managed health care providers have developed targeted programs for hypertension, hypercholesterolemia, and diabetes. In this study, the nurse-care managers were able to improve care across three of the major comorbid problems (hypertension, diabetes, and hypercholesterolemia) in patients who are at significant risk for CVD. As assessed by the computerized utilization database, there were no increases in physician visits for the intervention group. Although data were not available on the number of contacts made by diabetes care managers within the medical care system to usual care patients, it is likely that the intervention increased the number of nurse-care contacts.

Like many other studies of patients with diabetes, this population was very overweight and sedentary (mean BMI = 33 kg/m^2, maximum BMI = 56). The intervention could probably be improved by enhancing the nurse-care management of exercise and diet, as has been provided in other nurse-managed programs (13) or by adding other interventions such as more intensive monitoring and group support and including registered dieticians in the case management.

Our study also does not permit an analysis of the specific need for the various intervention components. An initial visit with the nurse-care manager is important to establish rapport, assess the patient, and set goals. The four group meetings were extremely popular with the patients, and it is necessary to provide extensive information about disease-related issues and management to patients; however, this might be done in more cost-effective ways, for instance, through on-line or other computer-assisted educational programs. Other health care professionals could also provide many aspects of the intervention.

The high levels of self-reported psychological functioning and self-management confidence were somewhat surprising, as were the significant improvements in mood in both control and intervention groups. Weinberger et al. (6) also found no change on the Short Form-36 in his nurse-coordinated intervention. The small number of untreated depressed patients did not allow for a comparison of the impact of the nurse-care management with usual care. However, the fact that all of these patients were willing to begin antidepressant medication, and the two patients identified as having alcohol problems were willing to enter therapy, suggests that nurse-care managers can play an important role in screening, referring, and even treating patients with comorbid psychiatric problems.

Although the intervention did not increase physician visits or alter days of hospitalization during the study compared with the year before, there were additional costs for providing the intervention, including the cost of the nurse-care manager's time, the additional medication, laboratory costs incurred by using the management algorithms, and costs related to higher rates of routine assessment and self-management. Aubert et al. (4) estimated that a nurse-case manager could maintain a case load of up to 300 patients. If their study results translated into equal changes in glycemic control in clinical practice, the intervention was cost-effective in terms of estimated reduced future medication costs related to treating complications of the illness (14). Since our results for glycemic control were similar, but proved to be better for lipids and achieved with less intensive effort, the intervention might also have a projected cost benefit that remains to be shown and requires more information on the true cost of the intervention.

We have shown that nurse-care managers working closely with the patients' primary care physicians and using evidence-based algorithms can improve medical outcomes in poorly controlled diabetic patients with significant comorbid conditions without increasing physician visits. The intervention needs to be enhanced, however, to have more impact on the psychosocial and lifestyle outcomes.

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