A Telephone-Delivered Intervention for Patients With NIDDM

Effect on coronary risk factors

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OBJECTIVE — To examine whether a telephone-delivered intervention (TDI), designed to improve glycemic control in patients with non-insulin-dependent diabetes mellitus (NIDDM), improved coronary risk factors in high-risk patients.

RESEARCH DESIGN AND METHODS — This randomized controlled trial involved 275 veterans with NIDDM followed in a general medical clinic. Intervention (TDI) patients were telephoned at least monthly by a nurse. Calls emphasized compliance with the medical regimen (diet, medications, and exercise), encouraged behavioral changes, and facilitated referrals to a dietitian or smoking cessation clinic. Control patients received no such calls. Baseline and 12-month follow-up measurements included fasting lipid profiles, weight, smoking status (self-reported; cessation verified by measurement of exhaled CO), adherence to diet and exercise (self-reported), appointments, and medications (hospital computerized data base).

RESULTS — After 12 months, equal numbers of obese patients in the two groups reported adhering to a diabetic diet and exercising, although more obese TDI patients had seen a dietitian (30 vs. 7%, $P = 0.003$). Weight loss was not seen in either group (-0.9 ± 5.3 vs. -0.1 ± 3.6 kg, $P = 0.202$). Hyperlipidemic TDI patients were more likely to see a dietitian (31 vs. 6%, $P = 0.003$) and receive lipid-lowering medications (22 vs. 9%, $P = 0.096$), but serum cholesterol reduction was similar between groups (-11.7 ± 33.4 vs. -4.3 ± 32.7 mg/dl, $P = 0.270$); comparable results were seen for high-density lipoprotein, low-density lipoprotein, and triglyceride levels. More TDI group smokers reported quitting (26 vs. 0%, $P = 0.033$), but the difference was not significant for CO-verified abstention (10 vs. 0%, $P = 0.231$).

CONCLUSIONS — The TDI improved self-reported adherence to regimens that might reduce coronary risk, but had little effect on objective measures of risk.

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NIDDM, non-insulin-dependent diabetes mellitus; TDI, telephone-delivered intervention; GMC, General Medical Clinic; VAMC, Department of Veterans Affairs Medical Center; OHA, oral hypoglycemic agent; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Non-insulin-dependent diabetes mellitus (NIDDM) is a prevalent condition, affecting 5–6% of adults in the U.S. (1). Coronary artery disease is the most common cause of death in these patients, who have a two- to threefold risk of coronary events compared with age-matched nondiabetic individuals (2). Other coronary risk factors often coexist with NIDDM. Approximately 50% of people with NIDDM have hypertension (3), and 75% are obese (at least 20% over ideal body weight) (4). Compared with the general population, NIDDM patients are as likely to have hypercholesterolemia and more likely to have hypertriglyceridemia (5). The prevalence of smoking is equal in diabetic and nondiabetic populations of similar age (6).

Whether improving glycemic control in NIDDM reduces the risk of coronary artery disease is not yet known, although several large studies have been undertaken to test this hypothesis (7,8). Modification of other coronary risk factors has been shown to reduce risk in the general population (9,10) and is advised in the diabetic population as well (11,12). Primary-care physicians, who care for most NIDDM patients (13), may lack the resources and incentives to provide ongoing support for the lifestyle changes necessary for patients to stop smoking, exercise more, or lose weight. Thus, one strategy to encourage patients to undertake such behavioral changes would be a low-cost intervention delivered between visits to primary-care physicians.

We conducted a randomized controlled trial of a telephone-delivered intervention (TDI), which had as its primary goal the improvement of glycemic control in a primary-care population of patients with NIDDM. This report examines whether the intervention, which had a positive effect on glycemic control (14), also improved other modifiable coronary risk factors such as body weight, serum lipids, and smoking status.

RESEARCH DESIGN AND METHODS

— The study was conducted in the General Medical Clinic (GMC) of the Durham Department of Veterans Affairs Medical Center (VAMC). Board-certified internal medicine faculty (who care for 75% of GMC patients) or internal medicine housestaff paired with faculty physicians provide longitudinal primary care to approximately 3,000 patients. An estimated 20% of GMC patients have diabetes, >90% of whom have NIDDM.

Patients were invited to participate in a randomized controlled trial to evaluate the impact on glycemic control of monthly telephone contacts by one of three diabetes nurses. The study was approved by the Durham VAMC Research and Human Subjects Committees.

Potential study patients were identified through computer audits of GMC patients who had ever filled a prescription for insulin or an oral hypoglycemic agent (OHA) at the Durham VAMC pharmacy, where all outpatients fill their prescriptions. Inclusion criteria were *1*) having NIDDM, defined as a history of OHA use or using insulin with no history of diabetic ketoacidosis and age at onset of diabetes ≥40 years; 2) currently using an OHA or insulin; 3) having access to a telephone; *4*) having had at least one GMC visit during the previous year and having a pending GMC appointment; and *5*) keeping a scheduled GMC appointment during a 6-month enrollment period in 1991. Exclusion criteria were *1*) being incompetent for interview (active psychosis or dementia); 2) residing in a nursing home; 3) being severely impaired in vision, hearing, or speech; *4*) receiving home health care; *5*) being terminally ill (criteria previously described) (15); or *6*) having diabetes caused by pancreatic insufficiency.

The computerized audit identified 526 potential study patients, whose medical charts were then audited for study eligibility and certain baseline data by one of three study nurses. After excluding ineligible patients, the remaining patients (n = 363) were contacted by letter, by telephone, or in the clinic to participate in the study; 56 were subsequently found to be ineligible. Of 307 patients meeting all study criteria, 275 (90%) gave informed consent and were enrolled in the study.

Demographic and medical data were collected from chart reviews and patient interviews (inter-rater reliability exceeded 95% during pilot testing of the instruments). After patients provided informed consent and baseline data were collected, they were randomly assigned to one of two study groups, using a permuted blocked randomization stratified by study nurse and hypoglycemic regimen. The study continued for 12 months, after which outcome measures were obtained. GMC physicians were unaware of study hypotheses addressing cardiac risk factors.

Measurements

Baseline data included sociodemographic information, medication use, self-reported compliance with diabetes regimen (medications, diet, exercise, and home glucose monitoring), and self-reported smoking status. Questions about compliance asked patients to consider the previous week; answers to questions about medications and home glucose monitoring were compared with computerized pharmacy records of medications and monitoring supplies; and compliance with diet and exercise were considered dichotomous variables depending on response to the questions, "Have you generally been sticking to your diabetic diet (exercise program)?" More detailed information about diet and exercise was obtained but could not objectively be verified. Self-reports of compliance were sought in a nonthreatening fashion and therefore considered as valid as any other measure (16). Satisfaction with health care was assessed using the Overall Satisfaction With Care item grouping of the Patient Satisfaction Questionnaire (17). The four items (rewritten to apply to Veterans Administration care) are each scored on a Likert scale of 1–5, with higher scores representing greater satisfaction with care; possible scores ranged from 4 (least satisfied) to 20 (most satisfied). Height and weight were measured using a balance scale (Health-o-Meter, Continental Scale, Chicago, IL). GHb was measured by affinity chromatography (Glyc-affin, Isolab, Akron, OH) and fasting lipid panels by enzymatic assay of total and high-density lipoprotein (HDL) cholesterol and triglycerides (Ectachem 700, Kodak, Rochester, NY). At 12-month follow-up, all study patients were interviewed using the same instruments by a research assistant, who was unaware of the study hypotheses and study group assignment. Weight, GHb, and fasting lipid profiles were measured again at follow-up. For patients who classified themselves as smokers at study entry and nonsmokers at follow-up, smoking status was verified at a subsequent GMC visit by measuring exhaled CO using a hand-held meter (BreathCO, Vitalograph, Lenexa, KS); nonsmoking was defined as exhaled CO <7 ppm. Ideal body weight was calculated in pounds using the 100 plus 5 rule for women and the 106 plus 6 rule for men (18) and then converted to kilograms. Follow-up interviews were obtained for 251 patients (91%) and follow-up laboratory analyses for 248 patients (90%).

High-risk subgroups were defined for each risk factor examined. Obesity was defined as being ≥120% of ideal body weight, the point at which mortality begins to increase in population studies (19). Hyperlipidemia was defined as meeting criteria of the National Cholesterol Education Project for high-risk total cholesterol, i.e., a total serum cholesterol level ≥200 mg/dl and two other coronary risk factors (diabetes and male sex) (20). Cigarette smokers were defined as those answering affirmatively at study enrollment to the question, "Do you smoke cigarettes?"

Table 1—*Characteristics of study patients*

	TDI group	Control group
n	204	71
Sociodemographic characteristics		
Age (years)	63.9 ± 8.6	63.2 ± 8.3
Gender (% male)	98.5	100
Race (% white)	60.8	57.7
Satisfaction with care score	14.1 ± 3.1	14.8 ± 3.1
Clinical characteristics		
% ideal body weight	130.6 ± 23.8	130.6 ± 19.2
% receiving insulin	48.5	42.3
% with hypertension	64.2	74.7
Fasting blood glucose (mg/dl)	185.2 ± 67.0	183.9 ± 75.8
GHb (%)	10.7 ± 3.3	10.7 ± 3.4
% reporting adherence to diet in the past week	61.8	56.3
% reporting exercising in the past week	43.1	45.1
% current smokers	23.0	25.4
Total cholesterol (mg/dl)	199.3 ± 42.0	207.1 ± 41.6
Triglycerides (mg/dl)	229.2 ± 196.0	223.6 ± 225.7
HDL cholesterol (mg/dl)	40.6 ± 11.3	42.3 ± 13.1
LDL cholesterol (mg/dl)	119.2 ± 36.9	129.1 ± 32.8

Data are means ± SD.

Study groups

A research nurse attempted to call TDI-group patients at least monthly, with each of three nurses following a panel of patients throughout the 12-month study. Telephone calls emphasized understanding of and compliance with the medical regimen prescribed by the GMC physician (diet, exercise, diabetic and other medications, and home glucose monitoring). Study nurses attempted to identify barriers to compliance, such as lack of knowledge about the regimen, poor understanding of the rationale for complying with the regimen, a patient being out of medications or supplies, or side effects of treatment. Lack of knowledge about the regimen was addressed directly during the phone call through clarification of previous physician instructions, while poor understanding of the reason for behavioral changes was addressed by pointing out the advantages of undertaking them (better glycemic control, improved symptoms, and well-being). Other barriers were reported to the GMC physician. The nurses reminded patients of upcoming clinic appointments. Patients who were smokers were reminded at each phone call of the health consequences of smoking, were advised to quit, were offered enrollment in a smoking cessation clinic, and were given positive reinforcement for efforts to quit. Patients with obesity or hyperlipidemia were encouraged to exercise and follow a hypocaloric diet and were offered an appointment with a dietitian. If a patient accepted the offer to attend the smoking cessation or dietitian clinic, the nurse facilitated the referral from the GMC physician.

Control patients received usual care, but no telephone calls from the study nurses. There was no systematic provider-initiated monitoring of health status between visits, and discussions of behavioral changes only occurred if the physician or patient initiated them during GMC visits.

Statistical analysis

Categorical variables (the percentage answering "yes" to questions of dietary adherence or exercise and the percentage of smokers who stopped during the study) were compared between groups at study completion by the χ^2 statistic. Continuous variables (lipid levels, weight, and satisfaction with care scores) were analyzed by calculating a change score for each patient (follow-up value minus enrollment value); mean change scores were compared between groups by two-tailed Student's *t* test. With 204 patients in the intervention group and 71 in the control group, the study had 80% power to detect a 12 mg/dl change in total cholesterol and >99% power to detect a 20 mg/dl change in the same variable.

RESULTS— Table 1 shows baseline characteristics of study subjects. The mean age was 63.7 years; 99% were men, and 60% were white. Patients were, on average, 30% over ideal body weight; the prevalence of hypertension was 67%. At study enrollment, 24% of patients were current smokers. Mean total cholesterol level was 201 mg/dl, mean triglyceride level was 226 mg/dl, mean HDL cholesterol level was 41 mg/dl, and mean low density lipoprotein (LDL) cholesterol level was 121 mg/dl. By self-report, 60% had adhered to a diabetic diet in the past week, and 44% had exercised. Mean satisfaction with care score was 14.3 (possible range 4–20). There were no statistically significant differences in baseline characteristics between the two groups at enrollment, although TDI patients had somewhat lower levels of total cholesterol (199 vs. 207 mg/dl) and LDL cholesterol (119 vs. 129 mg/dl).

As previously reported (14), the TDI group had somewhat improved glycemic control after 1 year compared with the control group (a mean reduction of 0.65% in GHb, $P = 0.048$). Table 2 shows the effect of the TDI on the first other modifiable coronary risk factor examined, obesity (being at least 120% of ideal body weight). More obese patients in the TDI group than in the control group met with a dietitian during the study (30 vs. 7%, $P = 0.003$). However, after 12 months, obese patients in the TDI

Table 2—*Effect of the intervention on obese patients*

	TDI group	Control group	*P* value
n	115	41	
Seen by dietician (%)	30	7	0.003
Adhering to diet (%)	72	69	0.713
Exercising (%)	59	51	0.380
Change in weight (kg)	−0.9 ± 5.3	−0.1 ± 3.6	0.202

Change in weight data are means ± SD. Obesity was defined as weight at study enrollment ≥120% of ideal body weight.

group were no more likely than control patients to state that they were adhering to a diabetic diet (72 vs. 69%, $P = 0.713$). Obese TDI patients were slightly more likely to report that they were exercising at the end of the study, but the difference between groups was not statistically significant (59 vs. 51%, $P = 0.380$). Furthermore, there was no significant weight loss in either group and no difference in weight change between the two groups (−0.9 ± 5.3 vs. −0.1 ± 3.6 kg, $P = 0.202$).

Hyperlipidemia (defined as total cholesterol level of at least 200 mg/dl) was found in approximately half of the patients. Although more lipid-lowering drugs were prescribed for hyperlipidemic patients in the TDI group during the study (22 vs. 9%, $P = 0.096$) and more TDI patients had dietitian appointments (31 vs. 6%, $P = 0.003$), there were no significant differences between groups in change scores for any serum lipid measurement (Table 3).

No nonsmokers reported that they had started smoking during the study. As shown in Table 4, there was no difference in the number of smokers who went to the smoking cessation clinic (21% of each group). No smokers in the control group reported that they had stopped smoking by the conclusion of the study, whereas 11 of 42 smokers in the TDI group reported quitting within the previous year ($P = 0.033$). However, when exhaled CO measurements were obtained on 10 of 11 quitters within 3 months after completion of the study, abstinence could only be verified in 4 of 10 (the 6 patients who had elevated exhaled CO levels admitted either falsely reporting smoking cessation or resuming smoking after study completion). If only 4 of 42 smokers are presumed to have truly stopped smoking in the TDI group, the difference between groups becomes statistically nonsignificant ($P = 0.231$).

There was a modest increase in satisfaction with care scores in the TDI group while the control group had a comparable decrease in satisfaction scores (0.45 ± 2.73 vs. −0.38 ± 2.86 U; $P = 0.04$ for between-group comparison).

CONCLUSIONS — Modifiable coronary risk factors are common in patients with NIDDM, and many of the lifestyle changes patients must make to improve their level of risk are identical to those required for improving glycemic control (adherence to a diet, exercising, and losing excess weight). Others, such as quitting smoking, do not have a direct impact on glycemic control but may lower the risk of diabetes-related complications such as lower-extremity amputations (21,22). For these reasons, interventions to lower coronary risk in NIDDM patients should be compatible with diabetes treatment regimens. Nevertheless, the necessary lifestyle changes require considerable sustained behavioral modification on the part of patients, and primary-care physicians may not have the time, skills, or incentives to provide ongoing support for these efforts. Frequent clinic visits to provide such feedback are time-consuming and expensive for patients. We therefore examined whether an inexpensive adjunct to primary-care physician visits, monthly telephone calls from a nurse emphasizing adherence to pharmacological and nonpharmacological facets of the medical regimen, would succeed in improving objective markers of coronary risk in this group with NIDDM. Similar TDIs have been shown to improve functional status in patients with osteoarthritis (23) and to increase rates of smoking cessation among postmyocardial infarction patients (24) and among non-ill smokers (25).

Our data suggest that the intervention, primarily designed to improve glycemic control, led to some improvement in self-reported adherence to behaviors that would tend to lower coronary risk, such as smoking cessation and receiving dietary advice. This finding was

Table 3—*Effect of the intervention on hyperlipidemic patients*

	TDI group	Control group	*P* value
n	97	34	
Seen by dietician (%)	31	6	0.003
% taking lipid-lowering medications	22	9	0.096
Change in total cholesterol (mg/dl)	−11.7 ± 33.4	−4.3 ± 32.7	0.270
Change in triglycerides (mg/dl)	−19.3 ± 209	−44.6 ± 250	0.572
Change in LDL cholesterol (mg/dl)	−8.0 ± 24.2	0.3 ± 28.2	0.161
Change in HDL cholesterol (mg/dl)	−2.7 ± 11.0	0.2 ± 7.4	0.378

Data are means ± SD. Hyperlipidemia was defined as a total cholesterol ≥200 mg/dl at study enrollment plus two coronary risk factors (diabetes and male sex).

Table 4—*Effect of the intervention on cigarette smokers*

	TDI group	Control group	*P* value
n	42	14	
% attending smoking cessation clinic	21	21	>0.9
% of smokers who quit (self-report)	26	0	0.033
% of smokers who quit (CO-verified)	9.5	0	0.231

Cigarette smokers were defined as patients answering "yes" at study enrollment to the question, "Do you smoke cigarettes?"

most striking in the case of cigarette smoking: 26% of smokers in the intervention group reported quitting by study conclusion, but only a 10% cessation rate could be verified biochemically. Rates of false reporting of smoking cessation tend to be greater in high-risk medical patients and in clinic-based interventions where the personnel who counsel smokers are also those who assess smoking status (26), conditions that apply to our trial (many of our patients viewed the close-out assistant as an affiliate of the study nurses, because of overlap of questions between the telephone and close-out protocols and the gender of the personnel). Although other authors have argued that misreporting smoking status should not be different between the intervention and control groups (27), our results suggest otherwise and verify the need for objective measures of behavior change. These results are consistent with those of Glasgow et al. (28), who showed that therapist contact increased self-reported smoking cessation rates of smokers who used behavior therapy books but did not significantly increase CO-verified cessation rates. That such discrepancies between self-report and objective measures are not limited to smoking status is also shown by our results for obesity and hyperlipidemia: despite intervention, patients having more dietitian vists and being somewhat more likely to report exercising, objective measures of the effectiveness of these behaviors (changes in weight or serum lipid levels) were not seen.

There may be several reasons why the TDI did not have a significant effect on objective measures of modifiable coronary risk factors. Long-term changes in lifestyle require a desire on the part of patients to change. Although our patients knew the study was designed to try to improve glycemic control, it seems unlikely that they were as motivated to undertake drastic changes in lifestyle as are, for example, patients who actively seek out a weight-loss clinic or a smoking cessation intervention. Numerous other factors are likely to influence compliance with medical care recommendations, including health beliefs, perception of psychological and other costs, satisfaction with care, and social support (29). We did find that the TDI was associated with improvement in satisfaction with care, a variable positively associated with compliance (29). However, the difference in satisfaction scores between the two groups may not have been large enough (although statistically significant) to have a major effect upon compliance.

Behavioral modification is most likely to succeed if health-care providers interact as a team (30) and if such interventions are tailored to the individual patient's needs and goals (31). Our findings are in distinct contrast to those of the Diabetes Control and Complications Trial, where weekly phone calls from a study nurse were probably an integral factor in the achievement and maintenance of good glycemic control in patients with IDDM (32). However, nurses in that trial were an active component of a patient-care team that also included dietitians, endocrinologists, and behavioral medicine specialists; intensively treated patients and all members of the health-care team had congruent goals, and the resources available for the trial allowed each patient's care to be individualized. In contrast, our nurses used a standard protocol for all telephone calls (although they attempted to tailor the calls to the individual patient's needs) and worked separately from the GMC so their efforts were not closely linked to the primary-care visit. Hence, our intervention may have been too generic to have been effective.

Finally, although our study could not demonstrate a strong effect on cardiac risk factors in patients with NIDDM, our results are similar to those of previous studies of risk modification in other populations of patients, even though such interventions may have been more intense than ours. For example, long-term sustained weight loss in obese patients has been an elusive goal (33,34), and low-intensity smoking cessation studies have shown equal or lower quit rates than we observed in our intervention group (35–37). We do not wish to suggest that efforts to reduce coronary risk in patients with NIDDM should be abandoned. Rather, our results and those of other researchers point to the need for further research toward developing more effective multidisciplinary interventions to address this major clinical problem.

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