Improving Combined Diabetes Outcomes by Adding a Simple Patient Intervention to Physician Feedback: A Cluster Randomized Trial

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ABSTRACT: **Background:** Research on synergistic effects of patient-targeted interventions combined with physician-targeted interventions has been limited.

Objectives: To compare a combined physician-patient intervention to physician feedback alone on a composite outcome of glycemic, lipid and blood pressure control.

Methods: In this cluster study 417 patients with adult-type 2 diabetes from four primary care clinics were randomized to receive either a physician-only intervention or a combined physician-plus-patient intervention. Physicians in all clinics received diabetes-related quality performance feedback during staff meetings. Patients at combined-intervention clinics also received a letter encouraging them to remind their doctors to address essential aspects of diabetes care at the next visit. At 1 year follow-up, outcome measurements included hemoglobin A1c, low density lipoprotein-cholesterol and systolic blood pressure: namely, the proportion of patients with HbA1c < 9%, LDL < 130 mg/dl and SBP < 140 mmHg both as separate outcomes and combined.

Results: After adjusting for patient characteristics and baseline measures, follow-up levels of HbA1c (7.5% vs. 7.8%, $P = 0.09$), LDL (104.7 vs. 110.7 mg/dl, $P < 0.05$) and SBP (135.6 vs. 139.9, $P = 0.10$) were marginally better for combined-intervention patients compared to physician-only intervention patients. Significantly more patients in the combined-intervention (38.8%) than physician-only intervention (24.2%) met all three targets (HbA1c < 9%, LDL < 130 mg/dl and SBP < 140 mmHg) as a single combined outcome (adjusted odds ratio 2.4, $P < .01$).

Conclusions: Compared to physician-feedback alone, a dual intervention combining a patient letter with physician feedback produced modest improvements in glycemic, lipid and blood pressure control individually, but substantial improvement in a combined measure of these three outcomes together. Using composite outcomes may detect meaningful improvements in the management of complex chronic disease.

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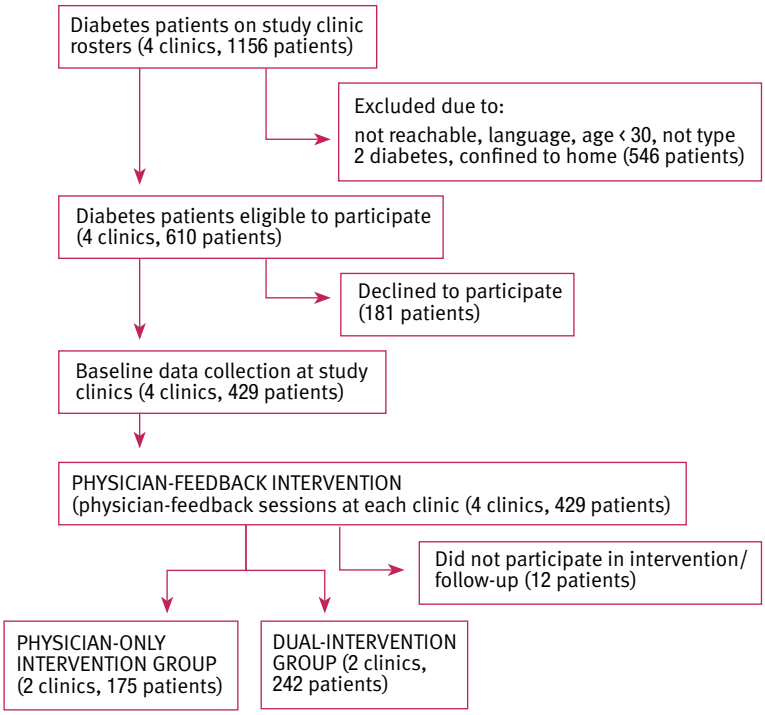
In addition to the routine performance of recommended tests, effective diabetes management requires control of hemoglobin HbA1c, lipids and blood pressure [1]. Despite the advent of efficacious medicines [2], there is a gap between ideal care and actual care in the achievement of recommended levels of multiple intermediate outcomes [3-5]. In an effort to improve the quality of diabetes care, various "system" interventions have been directed at influencing physicians. Such physician-targeted interventions have been shown to improve rates of performing recommended diagnostic tests, but have resulted only in modest positive effects on hemoglobin A1c levels [6-8]. The fact that improvement in the process is not consistently followed by improvement in the outcome suggests that the additional results from further testing may not be adequately dealt with during a busy clinic visit, particularly when many other dimensions of the disease require attention [1,9,10]. The challenge to improve diabetes care is complicated by the need to address the competing priorities of glycemic, lipid and blood pressure control simultaneously [11,12]. The difficulty of this challenge is demonstrated by the finding that only about 7% of diabetes patients in the United

HbA1c = hemoglobin A1c
LDL = low density lipoprotein
SBP = systolic blood pressure

Figure 1. Study flow diagram



States meet the American Diabetes Association targets for all three intermediate outcomes in combination (hemoglobin A1c, lipids, and blood pressure) [4,13,14]. This is despite the fact that dealing with these three dimensions is essential to prevent complications [12,15,16] and mortality [11]. To assess the degree to which the needs of complex patients are met, composite quality measures covering multiple dimensions of care have been proposed [17,19].

Because interventions aimed at activating patients to participate in their medical visits have been shown to improve quality of diabetes care [20,21], patient-targeted reminders have been proposed as a promising complement to physician-targeted interventions [1]. We hypothesized that patients in medical practices where physicians receive feedback on quality performance indicators, and patients receive a letter encouraging them to discuss a list of important diabetes-related issues with their doctors, will experience superior combined outcomes compared to patients in clinics who do not receive such a letter.

PATIENTS AND METHODS

In a cluster randomized study with the patient as the unit of analysis [Figure 1], two interventions were examined: a doctor-only intervention and a dual doctor-plus-patient intervention. The study was conducted from January 2000 through September 2003 in four clinics, two in the northern and two in the southern region of Israel. The clinics were randomly selected and staffed by board-certified specialists in family medicine or general internal medicine.

Lists of all known diabetic patients aged 30 years and older were compiled for each primary care practitioner in the four selected clinics. Patients were excluded if they had moved to another area, could not be contacted by phone after three attempts, spoke neither Hebrew nor Russian, were under the age of 30, were found on reappraisal of the clinical records not to have type 2 diabetes, or were confined to home because of poor health. All eligible type 2 diabetes patients from each clinic were approached sequentially over a 2 year span and asked to participate. Letters signed by the director of the clinic were sent to all eligible patients in the four clinics. In the letter, patients were notified about the project and that one of the research staff would contact them to invite them for an interview at the clinic. At least one week after the letters were sent, patients were contacted by phone to make an appointment for the interview. Patients who agreed to participate were enrolled when they arrived at the appointment after they were informed again by the research staff about the study and its requirements. Participating patients then signed the standard informed consent form approved by the Helsinki Committee. The study was approved by the Institutional Review Boards of the two regions.

One clinic from each region was randomly selected to receive the dual intervention, with the other receiving the doctor-only intervention. Randomization was conducted at the clinic level, rather than the patient level, to ensure that care delivered to patients in one intervention group was not influenced by a doctor's exposure to the other intervention group.

Prior to randomization, baseline data were collected from two primary sources: the computerized medical records of the clinics and a patient interview. Clinical and laboratory data were extracted from the computerized clinical medical records to obtain weight, height, HbA1c, low density lipoprotein-cholesterol, and blood pressure. HbA1c and lipid laboratory tests were centrally performed at the Soroka University Medical Center (for the southern clinics) and HaEmek Medical Center (for the northern clinics) using an automated SMA method. All participating patients were also interviewed at intake by trained personnel to obtain information on case-mix variables including age, gender, education level, duration of diabetes, use of insulin, language of interview, and self-reported health status.

Immediately following this baseline data collection, feedback sessions attended by all study physicians were held at each of the four clinics. These sessions included a presentation by one of the investigators (S.W.) on the proportion of their clinic's patients compared to patients at other study clinics who met quality targets [23] for each of the diabetes

process measures, which included checking blood pressure, laboratory tests for glycemic and lipid control, and foot and eye examinations, as well as intermediate outcome.

After the feedback session, two of the four clinics were randomly assigned to the physician-only intervention and no additional intervention was performed in these clinics. The remaining two clinics were assigned to the dual intervention, in which a patient reminder intervention was added to supplement the physician-intervention. Between 8 and 12 months after measures of diabetes process and outcome were again collected. In addition to mean levels of HbA1c, LDL and systolic blood pressure, we examined a set of outcome targets based on widely accepted quality assessment measures at the time of the study [23]: the proportion of patients with HbA1c > 9%, LDL < 130 mg/dl, and SBP < 140 mmHg.

The combined intervention included the same feedback sessions for physicians, followed by a letter and a follow-up telephone call to the patients. The letters, sent directly from each clinic's director, not from the research team, encouraged the patients to remind their physician at their next visit to address the items on a list of the essential aspects of diabetes care, including recommended lab tests, feet and eye exams and blood pressure. Follow-up telephone calls were made to patients in the dual-intervention clinics only to confirm that the letter was received. Patients in the doctor-only intervention clinics received the usual care and did not receive a reminder letter or a follow-up telephone call.

Baseline differences in mean values between treatment groups were compared with *t*-tests, and differences in proportions were compared by computing Z-scores. To account for group differences in patient characteristics and variation in baseline values, follow-up outcomes were compared using ordinary least-squares regression models entering treatment group as the independent variable, with a composite risk score and baseline values as covariates. The composite risk score derived from the patient interview was computed by creating an aggregate of age, gender, self-reported health status, duration of diabetes, language, and years of education using weights derived from a principal components analysis with a single factor solution.

We also examined the likelihood of patients meeting recommended targets used for quality assessment in the United States – HbA1c > 9.0%, LDL < 130 mg/dl and SBP < 140 mmHg [23] – both individually and in combination (i.e., meeting all three targets simultaneously). The relative likelihood of meeting one or more diabetes outcome target was estimated with logistic regressions controlling for the patient's status on the baseline values and the composite risk score. Although the models presented did not include imputed values, their results were corroborated by replicating the analyses with imputation of missing baseline values with group means, and by replicating the analyses for the subset of patients for whom there was no missing data. All analyses were performed in SPSS v.13.0.

RESULTS

Of the 1156 diabetes patients on the patient lists of participating clinics, 610 (53%) met the inclusion criteria [Figure 1]. Reasons for exclusion were: age < 30 years (17%), no answer to the telephone call (three attempts)/wrong telephone number (14.6%), language difficulties (12.3%), bedridden (3.5%), not diabetic (2.2%), moved to a different address (0.34%), deceased (1.4%), type 1 diabetic (0.08), or other reasons (1.1%) Of these eligible patients, 429 (70.3%) gave informed consent and were invited to participate in the intervention. A comparison between the 429 participating patients and the 727 patients who either were excluded or refused to participate did not show statistically significant differences in any of the demographic characteristics (data not shown). Of the participating patients, follow-up data were collected for 417 patients – 175 in the physician-only intervention and 242 in the dual intervention.

As seen in Table 1, there were no statistically significant baseline differences between the provider-only intervention and dual intervention in duration of diabetes or in measures of HbA1c, LDL and SBP. Compared to the dual-intervention group, fewer patients in the doctor-only intervention group were male. Doctor-only intervention patients were older and reported worse health status and fewer years of education than dual-intervention group patients. Mean intermediate outcomes at follow-up are summarized in Table 2. Adjusting

Table 1. Baseline patient characteristics by treatment group

	Doctor-only intervention (N=175)	Dual intervention (N=242)	Mean difference (95% CI)
Age (yrs)	65.8	63.1	-2.7 (-4.6, -0.7)**
Male (%)	36.6	55.8	19.1 (9.4, 28.9)***
Self-reported health (0–100 scale)	34.6	42.0	7.4 (3.3, 11.5)***
Duration of diabetes (yrs)	9.5	8.4	-1.1 (-2.6, 0.4)
Education (yrs)	9.1	11.0	1.8 (0.9, 2.8)***
On insulin (%)	10.6	8.3	-2.3 (-8.2, 3.6)
HbA1c level	8.1	8.1	-0.1 (-0.3, 0.5)
With A1c < 9 (%)	70.0	73.7	3.7 (-5.7, 13.1)
LDL (mg/dl)	119.9	121.0	1.1 (-8.0, 5.8)
With LDL < 130 (%)	66.0	64.4	-1.6 (-11.7, 8.4)
Systolic blood pressure (mmHg)	141.3	140.5	-0.8 (-3.6, 5.3)
With SBP < 140 (%)	41.1	43.4	2.3 (-9.1, 13.6)
With HbA1c < 9.0, LDL < 130 and SBP < 140 (%)	17.1	26.6	9.4 (-0.7, 19.5)

** $P < 0.01$, *** $P < 0.001$

Table 2. Mean follow-up values for intermediate outcomes at follow-up, by treatment group

	Unadjusted			Adjusted*			
Outcome	Doctor-only intervention (N=175)	Dual intervention (N=242)	Group difference (95% CI)	Doctor-only intervention (N=175)	Dual intervention (N=242)	Group difference (95% CI)	*P*
HbA1c (%)	7.8	7.7	-0.1 (-0.5, 0.2)	7.8	7.5	-0.3 (-0.5, 0.0)	0.085
LDL (mg/dl)	109.7	105.7	-4.0 (-10.4, 2.3)	110.7	104.7	-6.0 (-11.9, -0.2)	0.044
SBP (mmHg)	142.8	137.6	-5.3 (-9.4, -1.1)	139.9	135.6	-4.2 (-9.3, 0.8)	0.099

* Estimates from ordinary least-squares regression models controlling for baseline values and patient characteristics.
P values represent the likelihood of observing a non-zero difference in the adjusted outcome between the treatment groups.

Table 3. Relative likelihood of meeting follow-up outcome targets, by intervention group

Outcome target	Doctor-only intervention (N=175)	Dual intervention (N=242)	Unadjusted odds ratio (95% CI)*	*P*	Adjusted odds ratio (95% CI)**	*P*
A1c < 9 (%)	78.4	79.2	1.2 (0.7, 2.0)	0.606	1.1 (0.6, 2.1)	0.725
LDL < 130 (%)	76.8	81.2	1.5 (0.9, 2.6)	0.162	1.6 (0.9, 3.0)	0.138
SBP < 140 (%)	39.4	55.0	2.0 (1.2, 3.4)	0.007	2.2 (1.3, 3.8)	0.006
Combined outcome (% with A1c < 9, LDL < 130 and SBP < 140)	24.2	38.8	2.5 (1.4, 4.5)	0.002	2.4 (1.3, 4.6)	0.006

* Relative likelihood of a patient in the dual intervention versus the doctor-only intervention meeting the specified outcome targets estimated from logistic regression models controlling for baseline values. *P* values represent the likelihood of observing an odds ratio not equal to one.
** Odds ratios adjusted for baseline values and patient characteristics. CI = confidence interval

for baseline levels and patient characteristics, patients in the dual-intervention group had marginally lower HbA1c levels (7.5% vs. 7.8%, $P = 0.085$), significantly lower LDL (104.7 vs. 110.7 mg/dl, $P < 0.05$) and marginally lower systolic blood pressure (135.6 vs. 139.9 mmHg, $P = 0.099$) compared to the physician-only intervention group.

The combined outcome incorporating all three measures was also examined. As shown in Table 3, the direction of the group differences all favored the dual-intervention group, although only the proportion of patients with SBP < 140 mmHg was significantly larger in the dual versus the physician-only intervention group (adjusted odds ratio 2.2, $P < 0.01$). The proportion of patients meeting all three outcome targets of HbA1c < 9%, LDL < 130 mg/dl and SBP < 140 mmHg was significantly greater in the dual-intervention group (38.8%) than in the physician-only intervention group (24.2%; adjusted OR 2.4, $P < 0.01$). The percent of change from baseline to the end of the follow-up was statistically significant in the intervention (24.2% vs. 38.8% or 14.6%, $P = 0.003$) but not in the control group (17.1% vs. 24.2%, or 7.1%, $P = 0.11$). This pattern of findings persisted when rates of performance of recommended processes, which were comparable in the two groups, were controlled for and when missing values for baseline outcomes and patient characteristics were imputed.

OR = odds ratio

DISCUSSION

Our cluster randomized trial study, performed in community clinics, showed that the addition of a feasible, inexpensive patient-feedback intervention improved the combined intermediate diabetes outcome as compared to doctor-feedback alone. Although the magnitude of these improvements was modest for each individual outcome, the likelihood of simultaneously meeting all three outcome targets increased significantly with the addition of a patient letter. The fact that the direction of the observed group differences consistently favored the dual intervention suggests that this finding was not driven by a single outcome but by the accumulated contributions of all three.

This finding has important implications in terms of both the clinical benefit of the specific intervention studied and, more broadly, the measurement of quality of care. Optimal diabetes care requires consistent attention to multiple dimensions of care including glycemic, lipid and blood pressure control, in addition to prevention of eye, foot and renal complications. In a brief medical visit, some of these processes and outcomes may not have been addressed [9,24,25]. The intervention used here, combining a component that raises physician awareness with a patient component that provides reminders to act on that patient's own constellation of findings, appears to have been more effective than

doctor-feedback alone. The letter and the following phone call may have resulted in focusing the doctor on the patient's health priorities as well as on barriers to improving certain outcomes; or it may have resulted in getting the patient to be more motivated to achieve better outcomes supported by the mutuality of the agreement with the physician. However, we do not know the mechanism of the dual intervention.

Given the limited time a patient spends with the physician over a year's period, in contrast to the day-to-day burden of diet, medication adherence and exercise, it is not surprising that physician-interventions alone without patient participation fail to consistently achieve outcome goals for diabetes or other chronic diseases [7,8]. Intensive patient interventions, such as "Coached Care," have led to considerable improvements in intermediate diabetes outcomes by defining and encouraging an expanded patient role to maximize the benefit of medical visits [20,21]. Although intensive patient interventions may be optimal in many clinical contexts, they require considerable time and resources to implement. A simpler patient intervention combined with physician feedback may be useful and more feasible when resources are limited.

The results of the study point to the facilitating effect of a patient letter to complement a doctor-feedback intervention. In addition, they suggest the value of considering composite outcomes when evaluating treatment effects for patients with complicated conditions. Although gains in individual outcomes may be small, especially for patients whose levels are already moderately controlled at the outset, a combined measure can enhance the potential reduction in risk for microvascular and macrovascular complications that accrue by ameliorating, even modestly, the multiple dimensions of chronic disease management.

A limitation of this study is that since there were only 4 clinics and 15 physicians, the generalizability of the findings may be questioned. Because it was not possible to randomize patients to intervention conditions within clinics, we addressed this by first randomly selecting the four clinics from a pool of primary care facilities nationwide, and second, randomly assigning these clinics to intervention arms. Because there were baseline differences in patient characteristics including age, gender distribution, education and self-reported health status, we addressed the potential issue of sampling bias by reporting and controlling for baseline characteristics of the intervention and control clinics. The pattern of findings persisted when the analyses were replicated using imputed values for missing data.

Another limitation is that we do not know whether the gains will be sustained beyond the study period. Considerable research shows that, at least for most patients, only consistently reinforced interventions will have a long-term impact. Because sending patient reminder letters is affordable for most health management organizations, this intervention can be repeated periodically to reinforce its effect over time.

In conclusion, a brief letter coupled with a follow-up phone call was associated with improvement in a combined outcome, including blood pressure, hemoglobin A1c and LDL-cholesterol levels. Added to physician feedback, this simple and inexpensive approach may result in improved diabetes outcomes in locations where more intense intervention is not feasible. Furthermore, the use of combined outcomes may provide a more comprehensive assessment of future risk reduction than individual measures.

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