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Lifestyle Counseling in Routine Care and Long-Term Glucose, Blood Pressure, and Cholesterol Control in Patients With Diabetes

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OBJECTIVE—In clinical trials, diet, exercise, and weight counseling led to short-term improvements in blood glucose, blood pressure, and cholesterol levels in patients with diabetes. However, little is known about the long-term effects of lifestyle counseling on patients with diabetes in routine clinical settings.

RESEARCH DESIGN AND METHODS—This retrospective cohort study of 30,897 patients with diabetes aimed to determine whether lifestyle counseling is associated with time to A1C, blood pressure, and LDL cholesterol control in patients with diabetes. Patients were included if they had at least 2 years of follow-up with primary care practices affiliated with two teaching hospitals in eastern Massachusetts between 1 January 2000 and 1 January 2010.

RESULTS—Comparing patients with face-to-face counseling rates of once or more per month versus less than once per 6 months, median time to A1C <7.0% was 3.5 versus 22.7 months, time to blood pressure <130/85 mmHg was 3.7 weeks versus 5.6 months, and time to LDL cholesterol <100 mg/dL was 3.5 versus 24.7 months, respectively ($P < 0.0001$ for all). In multivariable analysis, one additional monthly face-to-face lifestyle counseling episode was associated with hazard ratios of 1.7 for A1C control ($P < 0.0001$), 1.3 for blood pressure control ($P < 0.0001$), and 1.4 for LDL cholesterol control ($P = 0.0013$).

CONCLUSIONS—Lifestyle counseling in the primary care setting is strongly associated with faster achievement of A1C, blood pressure, and LDL cholesterol control. These results confirm that the findings of controlled clinical trials are applicable to the routine care setting and provide evidence to support current treatment guidelines.

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Diabetes is increasingly common in the U.S. and worldwide (1,2). Elevated blood glucose, blood pressure, and LDL cholesterol are associated with increased risk for micro- and macrovascular complications, and their reduction decreases the risk (3–8). Nevertheless, most patients with diabetes do not have A1C, blood pressure, and LDL cholesterol under control (9,10).

American and European guidelines widely recommend diet, exercise, and

weight counseling with follow-up for patients with diabetes (11,12). Many short-term randomized clinical trials have shown that intensive lifestyle counseling interventions of up to 1 year in duration can lead to lower blood glucose (13–16) and blood pressure (17–21), but long-term data on the efficacy of lifestyle counseling are lacking (22–24). Furthermore, clinical trials typically involve resource-intensive interventions that may not be feasible in routine care, and the

efficacy of lifestyle counseling in everyday clinical practice remains questionable (25–27). Consequently, further evidence is needed to establish that lifestyle counseling as practiced in routine care improves the outcomes of patients with diabetes.

We therefore conducted a retrospective study of over 30,000 patients with diabetes and hyperglycemia, hypertension, and/or hyperlipidemia who received care in a primary care setting to test the hypothesis that higher rates of lifestyle counseling in routine care are associated with better diabetes control.

RESEARCH DESIGN AND METHODS

We conducted a retrospective cohort study to determine the optimal lifestyle counseling rate for patients with diabetes. We evaluated the relationship between the average counseling rate and time to A1C, blood pressure, and LDL cholesterol control.

Study cohort

Patients with diabetes seen by primary care physicians (PCPs) affiliated with the Brigham and Women's Hospital (BWH) and Massachusetts General Hospital (MGH) for at least 2 years between 1 January 2000 and 1 January 2010 were identified. Patients were included in the analysis if they were at least 18 years old, had a documented diagnosis of diabetes or hemoglobin A1C $\geq 7.0\%$, and at least one instance of A1C, blood pressure, or LDL cholesterol above treatment target. Patients with missing zip codes were excluded to enable adjustment for median household income by zip code.

This study was approved by the Partners HealthCare System institutional review board; the requirement for written informed consent was waived.

Study measurements

A single uncontrolled period served as the unit of analysis. We conducted four analyses: one for each of the three treatment targets (A1C, blood pressure, and LDL cholesterol) and a combined analysis

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that integrated all three. We used treatment goals recommended at the beginning of the study period: A1C <7.0% (28), blood pressure <130/85 mmHg (28,29), and LDL cholesterol <100 mg/dL (28). For analyses of individual treatment targets, an uncontrolled period started on the day when the relevant measurement (A1C, blood pressure, or LDL cholesterol for hyperglycemic, hypertensive, and hyperlipidemic periods, respectively) was noted to first be above the treatment target. The period ended on the first subsequent date when the measurement fell below the target. As patients' measures could fluctuate above and below target multiple times during the study period, one patient could contribute more than one period to the analysis. A combined uncontrolled period started on the first date when any of the three measures was above the treatment target and ended on the first subsequent

date when all of the measures were below their targets. Last known value was carried forward if all measurements were not available on the same date.

The lowest measurement on a given date was used in the analysis. Lowest blood pressure was defined as the blood pressure measurement with the lowest mean arterial pressure. Transient elevations were defined as periods that contained only a single elevated measurement that subsequently normalized without any medication intensification and were excluded from the analysis. Uncontrolled periods without at least one annual encounter with a BWH/MGH PCP were excluded. Periods without any medication information available in the electronic medical record (EMR) were excluded to enable inclusion of insulin treatment as a confounder variable in the analysis. Periods that contained multiple encounters with an endocrinologist were

excluded to focus the analysis on the primary care setting. Finally, hyperglycemic and hyperlipidemic periods where rate of change of A1C and LDL cholesterol, respectively, was greater than 3 SD from the mean were excluded to eliminate likely measurement errors from the analysis. Time to target for A1C, blood pressure, and LDL cholesterol during the respective uncontrolled periods was the length of the uncontrolled period. Lifestyle counseling instances were defined as distinct days when a PCP provided diet, exercise, or weight counseling during the uncontrolled period. Documentation of lifestyle counseling was computationally abstracted from the notes, including direct, such as "strongly encouraged more walking," and inferred, for example "weight has gone up," instances of lifestyle counseling, as previously described (30). We inferred lifestyle counseling if the subject was

Table 1—Patient characteristics

	Hyperglycemic period patients	Hyperlipidemic period patients	Hypertensive period patients	Combined uncontrolled period patients
<i>n</i>	17,404	18,639	30,784	30,897
Age (years)*	60.1 (13.8)	58.4 (13.4)	60.4 (13.9)	59.5 (14.1)
Women, <i>n</i> (%)	8,941 (51.4)	10,301 (55.3)	16,274 (52.9)	16,117 (52.2)
Race/ethnicity, <i>n</i> (%)				
White	10,756 (61.8)	11,528 (61.9)	20,882 (67.8)	20,937 (67.8)
Black	2,388 (13.7)	2,544 (13.7)	3,561 (11.6)	3,371 (10.9)
Hispanic	2,494 (14.3)	2,742 (14.7)	3,619 (11.8)	3,684 (11.9)
Other†	1,766 (10.1)	1,825 (9.8)	2,722 (8.8)	2,905 (9.4)
English as the primary language, <i>n</i> (%)	14,050 (80.7)	15,112 (81.1)	25,745 (83.6)	25,686 (83.1)
Health insurance, <i>n</i> (%)				
Private	6,946 (39.9)	8,128 (43.6)	12,611 (41.0)	12,885 (41.7)
Medicare	8,403 (48.3)	8,362 (44.9)	15,100 (49.1)	14,921 (48.3)
Medicaid	1,771 (10.2)	1,872 (10.0)	2,657 (8.6)	2,662 (8.6)
None/unknown	284 (1.6)	277 (1.5)	416 (1.4)	429 (1.4)
Median income by zip code (\$1,000)	52.0 (20.8)	52.5 (21.4)	53.0 (20.6)	53.3 (20.7)
Number of uncontrolled periods	1.6 (0.9)	1.4 (0.7)	3.7 (2.9)	2.3 (1.9)
Hemoglobin A1C (%)	7.7 (1.2)			7.2 (1.3)
Systolic blood pressure (mmHg)			130.5 (10.0)	129.5 (10.6)
Diastolic blood pressure (mmHg)			74.7 (6.7)	74.4 (6.8)
LDL cholesterol (mg/dL)		108.7 (23.2)		99.2 (27.5)
BMI (kg/m ²), mean (SD, % patients with measures)	32.8 (7.4, 63.2%)	32.6 (7.2, 67.2%)	32.6 (7.3, 66.3%)	32.4 (7.2, 65.1%)
Charlson comorbidity index	6.2 (4.6)	5.5 (4.5)	5.6 (4.5)	5.4 (4.5)
Follow-up time (months)	80.9 (28.2)	83.3 (28.1)	75.8 (29.5)	74.8 (29.4)
Total time above treatment target (months)	35.4 (30.0)	37.1 (28.2)	31.2 (24.7)	52.4 (33.6)

Data are mean (SD), unless otherwise indicated. *Age calculated at the start date of the first uncontrolled period. †Includes unknown.

referred to in a way that made it likely that it was discussed with the patient (e.g., not simply weight recorded in the vital signs section). The natural language processing software was previously validated and had a sensitivity and specificity that ranged between 91–97 and 88–94%, respectively. Weight counseling was limited to periods when the patient had BMI ≥ 30 kg/m². During the study period, none of the study practices had a program that encouraged a particular type of lifestyle counseling or monitored lifestyle counseling delivered by providers. To capture both face-to-face and remote interactions between patients and providers, we defined any note in the EMR as an encounter and any direct or inferred mention of lifestyle counseling in the notes as lifestyle counseling. Dates on which billing data included Current Procedural Terminology codes for evaluation and management were considered face-to-face lifestyle counseling encounters, whereas all other instances of lifestyle counseling were considered remote. Average lifestyle counseling rate was calculated by dividing the number of instances of lifestyle counseling by the period length. In our analyses, we categorized counseling rates as once or more per month, as less than once per month and once or more per 6 months, and as less than once per 6 months. Mean encounter interval was determined by dividing the period length by the number of encounters with PCPs during that period. Medication intensification was defined as initiation of a new or an increase in the dose of an existing medication (31). Medication intensification rate was defined as the number of unique dates per month on which at least one medication in the relevant class was intensified. The patient's PCP was defined as the physician in a primary care practice who had the most encounters with the patient during the uncontrolled period.

Demographic information, weight, height, blood pressure measurements, and medication and laboratory data were obtained from the EMR at Partners HealthCare—an integrated health care delivery network in eastern Massachusetts that includes BWH and MGH.

Statistical analysis

Summary statistics were constructed by using frequencies and proportions for categorical data and using means, SDs, medians, and ranges for continuous variables. Log-rank test was used to compare times to

A1C, blood pressure, and LDL cholesterol targets between different counseling rates.

Marginal Cox proportional-hazards model for clustered data (32) was used to estimate the association between time to target and lifestyle counseling rate while accounting for clustering within patient-provider pairs. Two models were run: one with an overall lifestyle counseling rate and one with separate rates for face-to-face and remote lifestyle counseling. The models also adjusted for demographic confounders (age, sex, race, primary language, health insurance, and median income by zip code) as well as a patient's Charlson comorbidity index (33) for the period of the study, insulin administration as a marker of severity of disease (in hyperglycemic and combined uncontrolled periods), PCP encounter frequency,

medication intensification rate, presence of obesity during the period, A1C and LDL cholesterol measurement rate and maximum A1C, systolic blood pressure, diastolic blood pressure, and LDL cholesterol (where appropriate). P values were obtained using a type III test.

All analyses were performed with SAS statistical software, version 9.2 (SAS Institute, Inc., Cary, NC).

RESULTS—We identified 37,863 adults with diabetes who were regularly seen by BWH or MGH PCPs and had experienced at least one hyperglycemic, hypertensive, or hyperlipidemic period (Supplementary Fig.). We excluded 6,702 hyperglycemic, 5,760 hypertensive, and 6,428 hyperlipidemic patients because of treatment by endocrinologists; no PCP at BWH or MGH;

Table 2—Uncontrolled period characteristics

	Hyperglycemic periods	Hyperlipidemic periods	Hypertensive periods	Combined uncontrolled periods
Study periods, n	26,984	26,893	112,716	72,532
Period length (months)	22.8 (24.9)	25.7 (25.0)	8.5 (11.7)	22.3 (28.2)
Average initial hemoglobin A1C (%)	8.1 (1.4)			
Average initial LDL cholesterol (mg/dL)		126.8 (25.4)		
Average initial systolic blood pressure (mmHg)			140.0 (12.8)	
Average initial diastolic blood pressure (mmHg)			78.1 (10.7)	
Average maximum hemoglobin A1C (%)	8.7 (1.9)			7.8 (2.0)
Average maximum LDL cholesterol (mg/dL)		136.6 (30.5)		111.2 (40.4)
Average maximum systolic blood pressure (mmHg)			148.4 (17.4)	149.3 (19.6)
Average maximum diastolic blood pressure (mmHg)			83.8 (10.5)	84.9 (10.9)
Periods where treatment target was reached, n (%)	18,526 (68.7)	20,903 (77.8)	108,737 (92.1)	52,109 (71.9)
Rate of medication intensification per month	0.09 (0.14)	0.06 (0.12)	0.22 (1.1)	0.17 (0.84)
Rate of measure testing per month	0.23 (0.14)	0.17 (0.17)	1.0 (1.6)	
Rate of face-to-face lifestyle counseling per month	0.24 (0.26)	0.20 (0.23)	0.36 (0.97)	0.24 (0.74)
Rate of remote lifestyle counseling per month	0.12 (0.20)	0.09 (0.18)	0.20 (0.69)	0.18 (0.60)
Encounter interval (months)	1.9 (1.7)	2.3 (1.9)	1.5 (1.5)	1.9 (1.8)
Periods with patients on insulin, n (%)	7,194 (26.7)			13,646 (18.8)
Periods with patients who are obese, n (%)	15,469 (57.3)	15,608 (58.0)	63,837 (56.6)	39,483 (54.4)

Data are mean (SD), unless otherwise indicated.

no medication records; only transient elevations in A1C, blood pressure, and LDL cholesterol; suspected A1C or LDL cholesterol measurement errors; and missing demographic information. The remaining 17,404 hyperglycemic, 30,784 hypertensive, and 18,639 hyperlipidemic patients (a total of 30,897 unique individuals) were included in the study.

Study patients (Table 1) did not have their A1C, blood pressure, or LDL cholesterol under control 71.3% of the time, and 66% of patients never achieved full control during the study period. Their mean initial A1C, blood pressure, and LDL cholesterol at the beginning of the respective

uncontrolled periods was 8.1%, 140/78 mmHg, and 126.8 mg/dL (Table 2). Subsequently median times to reach treatment targets ranged from 19 weeks (for hypertensive patients) to over 16 months (for hyperlipidemic patients). Hyperglycemic patients had A1C above target a mean of 46.5% of the time, hypertensive patients had uncontrolled blood pressure 42.0% of the time, and hyperlipidemic patients had elevated LDL cholesterol 46.7% of the time.

Median face-to-face lifestyle counseling rates ranged from once every 5.3 months for hyperglycemic periods to once every 8 months for hypertensive periods, whereas

median remote lifestyle counseling rates ranged from once every 25 months for hyperglycemic periods to never for hypertensive periods (Table 2). Mean times between patient encounters with a PCP were 1.9 months when hyperglycemic, 1.5 months when hypertensive, and 2.3 months when hyperlipidemic. During hyperglycemic periods, A1C testing occurred on average just over once every 4 months, blood pressure was measured once every month during hypertensive periods, and LDL cholesterol was measured once every 6 months during hyperlipidemic periods. Antihyperglycemic medications were intensified on average just over once every 11 months,

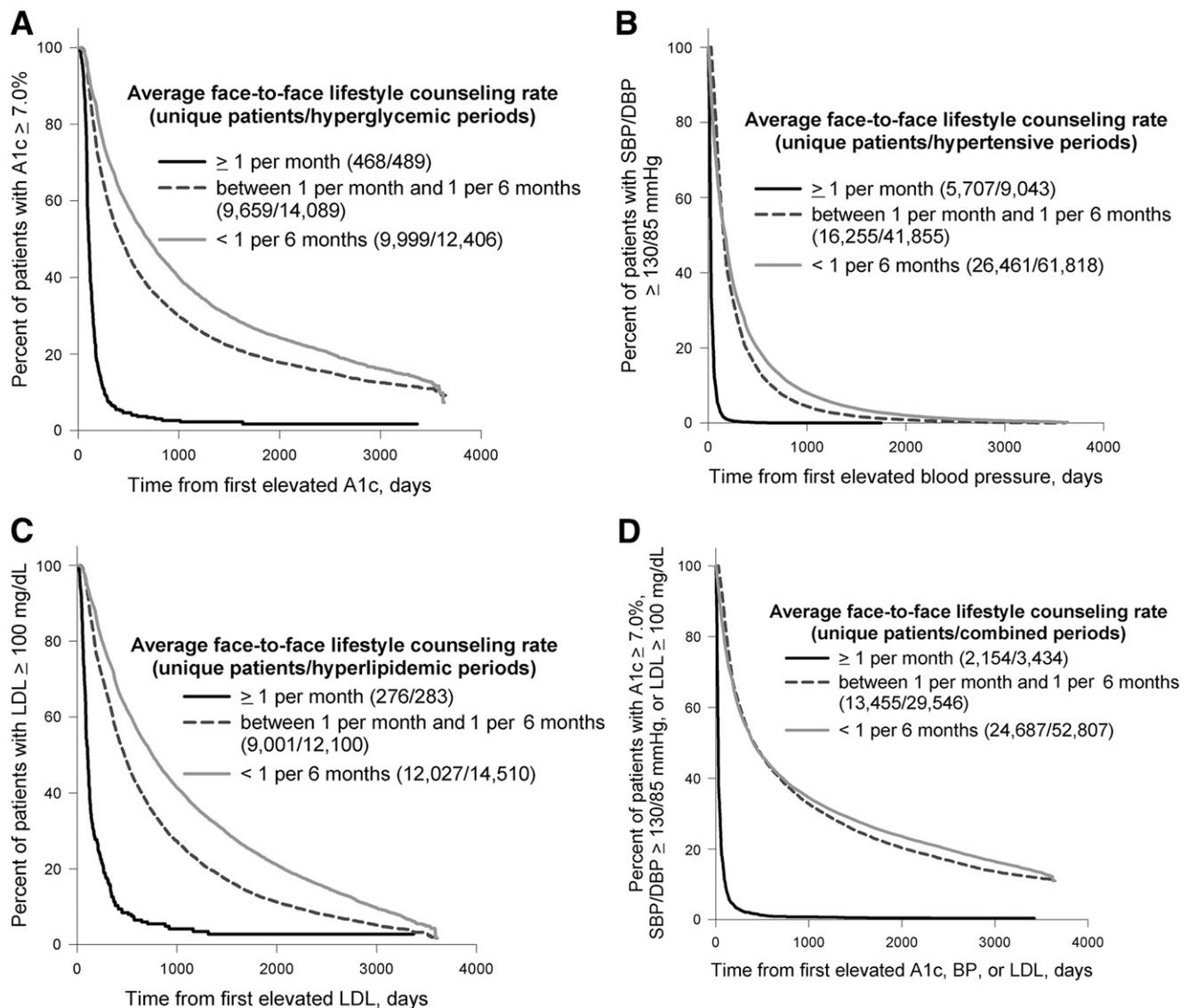


Figure 1—Lifestyle counseling frequency and time to treatment target. Kaplan-Meier curves for time to treatment target from first elevated A1C, blood pressure, or LDL cholesterol were plotted for different average counseling rates. Distinct uncontrolled periods (from the first elevated to the first normal measurement) for the same patient were analyzed separately. A: Lifestyle counseling frequency and time to A1C target. B: Lifestyle counseling frequency and time to blood pressure target. C: Lifestyle counseling frequency and time to LDL cholesterol target. D: Lifestyle counseling frequency and time to combined target. DBP, diastolic blood pressure; LDL, LDL cholesterol; SBP, systolic blood pressure.

antihypertensive medications once every 4.5 months, and antihyperlipidemic medications almost once every 17 months. Overall, patients with at least one of the measurements above target had their treatment intensified on average once every 6 months.

Lifestyle counseling rate and time to treatment target achievement

In all treatment categories, time to treatment target rose progressively at the less frequent rates of lifestyle counseling (Fig. 1). Compared with patients with mean face-to-face counseling rate of once or more per month, median times to A1C target for patients whose mean counseling rates were between once per 1–6 months and less than once per 6 months were 3.5 months (95% CI 3.2–3.7) vs. 14.0 (13.6–14.5) vs. 22.7 (21.8–23.5); time to blood pressure target was 3.7 weeks (3.6–3.7) vs. 5.1 months (5.1–5.2) vs. 5.6 (5.5–5.7) months and time to LDL cholesterol target was 3.5 months (3.0–3.8) vs. 15.6 (15.2–16.0) vs. 24.7 (24.1–25.4), respectively. For all treatment targets combined, median time to target was 3.9 (3.7–4.0) weeks vs. 13.5 months (13.0–13.9) vs. 13.1 (12.9–13.5) with mean face-to-face counseling rates of once or more per month versus once per 1–6 months versus less than once per 6 months.

As counseling rates decreased, the proportion of patients who never reached treatment targets rose steadily. Comparing patients with mean face-to-face counseling rates of once or more per month to between once per 1–6 months and less than once per 6 months, uncontrolled periods that never reached treatment target increased from 11.0 to 28 to 35.9% for hyperglycemic patients, from 5.63 to 7.2 to 8.86% for hypertensive patients, and from 15.6 to 18.2 to 25.8% for hyperlipidemic patients. For all treatment targets combined, the proportion of uncontrolled periods that never achieved all targets was 9.3% for counseling rates of once or more per month versus 26.0% for counseling rates between once per 1–6 months versus 30.5% for counseling rates of less than once per 6 months.

In multivariable Cox proportional hazards models adjusted for demographic characteristics, presence of obesity during the uncontrolled period, Charlson comorbidity index, insulin administration (in hyperglycemic and combined uncontrolled periods), maximum A1C, systolic blood pressure, diastolic blood pressure, and LDL cholesterol (where relevant), rate

Table 3—Effects of patient and treatment characteristics on time to treatment target

	Hazard ratio	95% Confidence limits		P value (χ^2)
Hyperglycemic periods				
Normalized maximum A1C, per 1% increase	0.539	0.528	0.550	<0.0001
Normalized age, per 1-year increase	0.993	0.991	0.994	<0.0001
Female	0.881	0.851	0.911	<0.0001
Non-English speaker	0.990	0.936	1.046	0.7098
Caucasian	1.000			
Black	1.115	1.061	1.171	<0.0001
Hispanic	1.099	1.028	1.174	0.0058
Asian	1.019	0.934	1.112	0.6658
Other/unknown	0.987	0.919	1.061	0.7310
Income, per \$1,000 increase	0.999	0.999	1.000	0.1831
Nonprivate insurance	0.965	0.926	1.005	0.0853
On insulin	0.630	0.602	0.659	<0.0001
PCP encounter interval, log(months)	0.803	0.770	0.837	<0.0001
Obesity during period	0.887	0.856	0.920	<0.0001
Charlson comorbidity index	1.016	1.011	1.020	<0.0001
Rate of A1C testing, per month	29.812	19.482	45.620	<0.0001
Rate of antihyperglycemic medication intensification, per month	2.727	2.156	3.450	<0.0001
Rate of face-to-face lifestyle counseling, per month	1.705	1.422	2.044	<0.0001
Rate of remote lifestyle counseling, per month	1.699	1.488	1.941	<0.0001
Hypertensive periods				
Normalized maximum systolic blood pressure, per 1-mmHg increase	0.968	0.968	0.969	<0.0001
Normalized maximum diastolic blood pressure, per 1-mmHg increase	0.975	0.974	0.976	<0.0001
Normalized age, per 1-year increase	0.995	0.994	0.996	<0.0001
Female	0.938	0.921	0.954	<0.0001
Non-English speaker	1.035	1.006	1.065	0.0179
Caucasian	1.000			
Black	1.150	1.121	1.180	<0.0001
Hispanic	1.108	1.072	1.144	<0.0001
Asian	1.175	1.120	1.233	<0.0001
Other/unknown	1.049	1.010	1.090	0.0128
Income, per \$1,000 increase	1.000	1.000	1.000	0.9251
Nonprivate insurance	0.997	0.977	1.018	0.7828
PCP encounter interval, log(months)	0.302	0.298	0.308	<0.0001
Obesity during period	0.895	0.879	0.910	<0.0001
Charlson comorbidity index	1.009	1.007	1.012	<0.0001
Rate of antihypertensive medication intensification, per month	1.625	1.568	1.685	<0.0001
Rate of face-to-face lifestyle counseling, per month	1.267	1.235	1.301	<0.0001
Rate of remote lifestyle counseling, per month	1.022	0.981	1.064	0.2933
Hyperlipidemic periods				
Normalized maximum LDL cholesterol, per 1-mg/dL increase	0.974	0.972	0.975	<0.0001
Normalized age, per 1-year increase	1.007	1.005	1.008	<0.0001
Female	0.885	0.856	0.916	<0.0001
Non-English speaker	1.088	1.034	1.144	0.0012
Caucasian	1.000			
Black	1.088	1.037	1.140	0.0005
Hispanic	1.142	1.077	1.210	<0.0001
Asian	1.150	1.062	1.245	0.0006
Other/unknown	1.057	0.968	1.153	0.2151

Table 3—Continued

	Hazard ratio	95% Confidence limits		P value (χ^2)
Income, per \$1,000 increase	1.001	1.000	1.002	0.0834
Nonprivate insurance	0.992	0.952	1.032	0.6808
PCP encounter interval, log(months)	0.720	0.691	0.750	<0.0001
Obesity during period	0.888	0.847	0.932	<0.0001
Charlson comorbidity index	1.009	1.005	1.013	<0.0001
Rate of LDL cholesterol testing, per month	257.64	114.99	577.26	<0.0001
Rate of antihyperlipidemic medication intensification, per month	3.600	1.950	6.644	<0.0001
Rate of face-to-face lifestyle counseling, per month	1.403	1.141	1.726	0.0013
Rate of remote lifestyle counseling, per month	1.215	1.054	1.400	0.0073
Combined uncontrolled periods				
Normalized maximum A1C, per 1% increase	0.675	0.667	0.683	<0.0001
Normalized maximum systolic blood pressure, per 1-mmHg increase	0.979	0.979	0.980	<0.0001
Normalized maximum diastolic blood pressure, per 1-mmHg increase	0.978	0.976	0.979	<0.0001
Normalized maximum LDL cholesterol, per 1-mg/dL increase	0.983	0.983	0.984	<0.0001
Normalized age, per 1-year increase	0.997	0.996	0.998	<0.0001
Female	0.919	0.899	0.940	<0.0001
Non-English speaker	1.037	0.997	1.078	0.0693
Caucasian	1.000			
Black	1.252	1.208	1.298	<0.0001
Hispanic	1.187	1.133	1.244	<0.0001
Asian	1.160	1.088	1.238	<0.0001
Other/unknown	1.060	1.009	1.114	0.0204
Income, per \$1,000 increase	1.002	1.001	1.002	<0.0001
Nonprivate insurance	1.011	0.985	1.037	0.4155
On insulin	0.894	0.866	0.923	<0.0001
PCP encounter interval, log(months)	0.726	0.719	0.734	<0.0001
Obesity during period	0.962	0.941	0.984	0.0007
Charlson comorbidity index	1.037	1.034	1.040	<0.0001
Rate of A1C testing, per month	1.113	1.069	1.159	<0.0001
Rate of LDL cholesterol testing, per month	1.160	1.122	1.200	<0.0001
Rate of antihyperglycemic medication intensification, per month	1.480	1.205	1.817	0.0002
Rate of antihypertensive medication intensification, per month	1.255	1.192	1.321	<0.0001
Rate of antihyperlipidemic medication intensification, per month	0.955	0.902	1.010	0.1045
Rate of face-to-face lifestyle counseling, per month	1.937	1.836	2.044	<0.0001
Rate of remote lifestyle counseling, per month	1.615	1.560	1.673	<0.0001

of A1C and LDL cholesterol measurement (where relevant), visit frequency, and medication intensification, one additional episode of face-to-face lifestyle counseling per month was associated with hazard ratios of 1.7 for A1C control ($P < 0.0001$) (Table 3), 1.3 for blood pressure control ($P < 0.0001$), and 1.4 for LDL cholesterol control ($P = 0.0013$). In multivariable analysis of combined uncontrolled periods, an increase of one face-to-face lifestyle counseling instance per month was

associated with a hazard ratio of 1.9 for achieving control of all treatment targets ($P < 0.0001$). For most measures, remote lifestyle counseling rates were also associated with faster time to target, but hazard ratios were smaller than those for face-to-face lifestyle counseling. A combined face-to-face and remote lifestyle counseling rate analysis was also conducted; results for this multivariable analysis are provided in Supplementary Appendix A.

CONCLUSIONS—In this large, retrospective study, we have demonstrated a strong association between lifestyle counseling and glucose, blood pressure, and LDL cholesterol control in patients with diabetes. This association was independent of other treatment processes that could colocalize with lifestyle counseling, including frequency of patient-provider encounters, medication intensification, and rates of A1C or LDL cholesterol measurement.

Several clinical trials have previously documented the benefit of lifestyle counseling on control of glucose (13–16) and blood pressure (17–21), but many providers question whether results of expensive and tightly controlled clinical trials apply to their practice. This study provides evidence for the efficacy of lifestyle counseling as practiced in routine patient care and lends support to the current treatment guidelines for patients with diabetes.

Few clinical trials of lifestyle counseling had follow-up longer than 12 months (21); this study, with an average length of follow-up time per patient of almost 7 years, provides evidence for long-term effects of lifestyle counseling. This is particularly important because some studies suggest that effects of intensive diet and exercise interventions may not be durable (24,34,35). Our findings suggest that, on the contrary, persistent lifestyle counseling has lasting effects. Our results confirmed that intensive counseling is needed to achieve benefits: the effects of lifestyle counseling were particularly pronounced in patients who were counseled at least once a month.

Studies have shown that lifestyle counseling in the U.S. remains inadequate (36–39). Despite the focus on lifestyle changes in many treatment guidelines, one study showed no difference in prevalence of exercise counseling in a sample of the U.S. population in 2002 compared with 1995 (39). Further education of physicians on the importance of lifestyle counseling and its positive impact on patient behavior and health outcomes may be necessary. Physicians may provide more counseling to underserved populations if made aware that patients with lower income, lower education level, who are male (37) and non-English speaking (38) receive lifestyle counseling at lower rates, compared with other equally high-risk patients.

Lifestyle counseling is time consuming. Therefore, implementation of current guidelines may require modification of the prevalent physician-patient treatment care model. One option may be to increase the

role of midlevel providers, such as nurse practitioners, physician assistants, nutritionists, or exercise physiologists. Another option may be to implement group counseling sessions in order to more efficiently educate and address patients' concerns.

This study used advanced computational technology that permitted cost- and time-efficient analysis of thousands of patient records, including examination of hundreds of thousands of narrative provider notes in a matter of hours. In the future, similar technologies could also be used to monitor quality of patient care and/or supply feedback to providers.

Our study had several limitations. The software we used to identify documentation of lifestyle counseling did not provide details on the specific counseling approach or the type of diet or exercise recommended to the patient. However, little evidence exists for superiority of any one approach over the others (24,26). It is therefore likely that multiple different counseling techniques can be successful, and specific type of counseling should be chosen in accordance with the particular patient and clinical circumstances. Information on the extent to which counseling followed a structured format (e.g., 5As) was not obtained because it is frequently absent in narrative documentation (40). The software we used did not distinguish between lifestyle counseling aimed to address hyperglycemia, hypertension, and hyperlipidemia severally, which may have led to an overestimate of lifestyle counseling rates associated with any one uncontrolled period. However, this lack of specificity should have biased our findings toward the null hypothesis. In our analysis, we did not analyze individual effects of diet, exercise, and weight counseling. However, their effects are likely overlapping because both diet and exercise, for example, can lead to weight loss. Furthermore, the best approach to counseling may differ depending on the individual patient and their readiness to change, rendering any statement about relative efficacy of different counseling types moot. We therefore chose to combine all lifestyle counseling into a single measure to avoid this type of confounding. The retrospective nature of this study does not allow us to make causal inferences about the relationship between counseling rates and time to glucose, blood pressure, and LDL cholesterol control in patients with diabetes. It could also have led to an analytical bias. For example, when lifestyle counseling is sparse, shorter uncontrolled periods

are more likely to have had no counseling episodes. However, this bias would have predisposed against the strong inverse association between lifestyle counseling and the length of uncontrolled periods that we have found. Furthermore, most uncontrolled periods in our study were substantially longer than the average observed rate of lifestyle counseling, making an artifactual association between lifestyle counseling rate and the length of uncontrolled period unlikely. Additionally, we were unable to distinguish between patients with type 1 and type 2 diabetes; however, the majority of patients in this population have type 2 diabetes, so our findings may not be applicable to patients with type 1 diabetes.

In summary, this large long-term retrospective study found that lifestyle counseling is associated with faster achievement of A1C, blood pressure, and LDL cholesterol control in routine patient care, consistent with findings of randomized controlled studies. Monthly lifestyle counseling was associated with a particularly strong effect and could be recommended for patients at particularly high risk of complications from uncontrolled diabetes. Interventional studies are needed to further establish optimal type and frequency of lifestyle counseling and its effects on the micro- and macrovascular complications of diabetes.

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F.M. conducted data analysis and drafted the manuscript. M.S. assisted in study design, provided biostatistical support, and critically reviewed the manuscript. A.T. designed the study, obtained funding, and critically reviewed the manuscript. F.M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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