Lifestyle Counseling and Long-term Clinical Outcomes in Patients With Diabetes

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OBJECTIVE

To investigate the relationship between lifestyle counseling in primary care settings and clinical outcomes in patients with diabetes.

RESEARCH DESIGN AND METHODS

We retrospectively studied hyperglycemic adults with diabetes treated at primary care practices between 2000 and 2014. We analyzed the relationship between frequency of lifestyle counseling (identified using natural language processing of electronic notes) and a composite outcome of death and cardiovascular events during subsequent follow-up.

RESULTS

Among patients with monthly counseling or more, 10-year cumulative incidence of the primary outcome was 33.0% compared with 38.1% for less than monthly counseling (P = 0.0005). In multivariable analysis, higher frequency of lifestyle counseling was associated with lower incidence of the primary outcome (hazard ratio 0.88 [95% CI 0.82–0.94]; $P < 0.001$).

CONCLUSIONS

More frequent lifestyle counseling was associated with a lower incidence of cardiovascular events and death among patients with diabetes.

The risk of cardiovascular events is increased by 60% in patients with diabetes (1). Elevated blood glucose levels in patients with diabetes are associated with higher cardiovascular risk (2). Pharmacological reduction in blood glucose levels decreases this risk (3,4). Intensive lifestyle interventions are also effective at lowering blood glucose (5–8). However, there remains uncertainty about whether lifestyle interventions can reduce cardiovascular risk or mortality among patients with diabetes.

It was previously shown that documentation of counseling by health care providers in routine care can be computationally identified in electronic medical record (EMR) notes using natural language processing (9,10). Subsequent research demonstrated that lifestyle counseling identified in this way is associated with improvement of blood glucose control (11,12). We therefore conducted this study to determine whether lifestyle counseling in routine care is associated with lower cardiovascular risk and mortality in patients with diabetes.

RESEARCH DESIGN AND METHODS

Study Cohort

Study participants included adults (≥18 years old) with uncontrolled (HbA_{1c} ≥7.0% [53 mmol/mol]) diabetes who were followed in primary care clinics affiliated with two academic medical centers between 2000 and 2014. The study design included three

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stages: a run-in period, a treatment assessment period, and an outcome ascertainment period. The run-in period began 12 months before cohort entry. The 2-year treatment assessment period started on the date of cohort entry. The outcome ascertainment period began at the end of the treatment assessment period and lasted until study exit. This study was approved by the institutional review board at the Partners HealthCare System (Boston, MA) with a waiver of informed consent.

Study Measurements

Patients' baseline characteristics were assessed at the end of the run-in period. The treatment assessment period was used to calculate the predictor variable (frequency of lifestyle counseling) and other treatment characteristics. Lifestyle counseling frequency was measured during the hyperglycemic periods (while HbA_{1c} $\geq$7.0% [53 mmol/mol] [13]) of the treatment assessment period.

Frequency of lifestyle counseling was calculated as the mean monthly number of primary care clinic notes during the hyperglycemic periods in which diet, exercise, or weight loss counseling were documented (11). Documentation of lifestyle counseling was identified in EMR provider notes using a previously validated natural language processing algorithm (9). Time-weighted average HbA_{1c} was calculated using the trapezoid rule.

The composite primary outcome was the time to the first of the following: a cardiovascular event (myocardial infarction, stroke, hospitalization for angina) or death as a result of any cause. Time to death and time to the first cardiovascular event served as secondary outcomes.

Statistical Analysis

Cox proportional hazards models were used to estimate the association between lifestyle counseling frequency and patient outcomes while accounting for clustering within providers. The

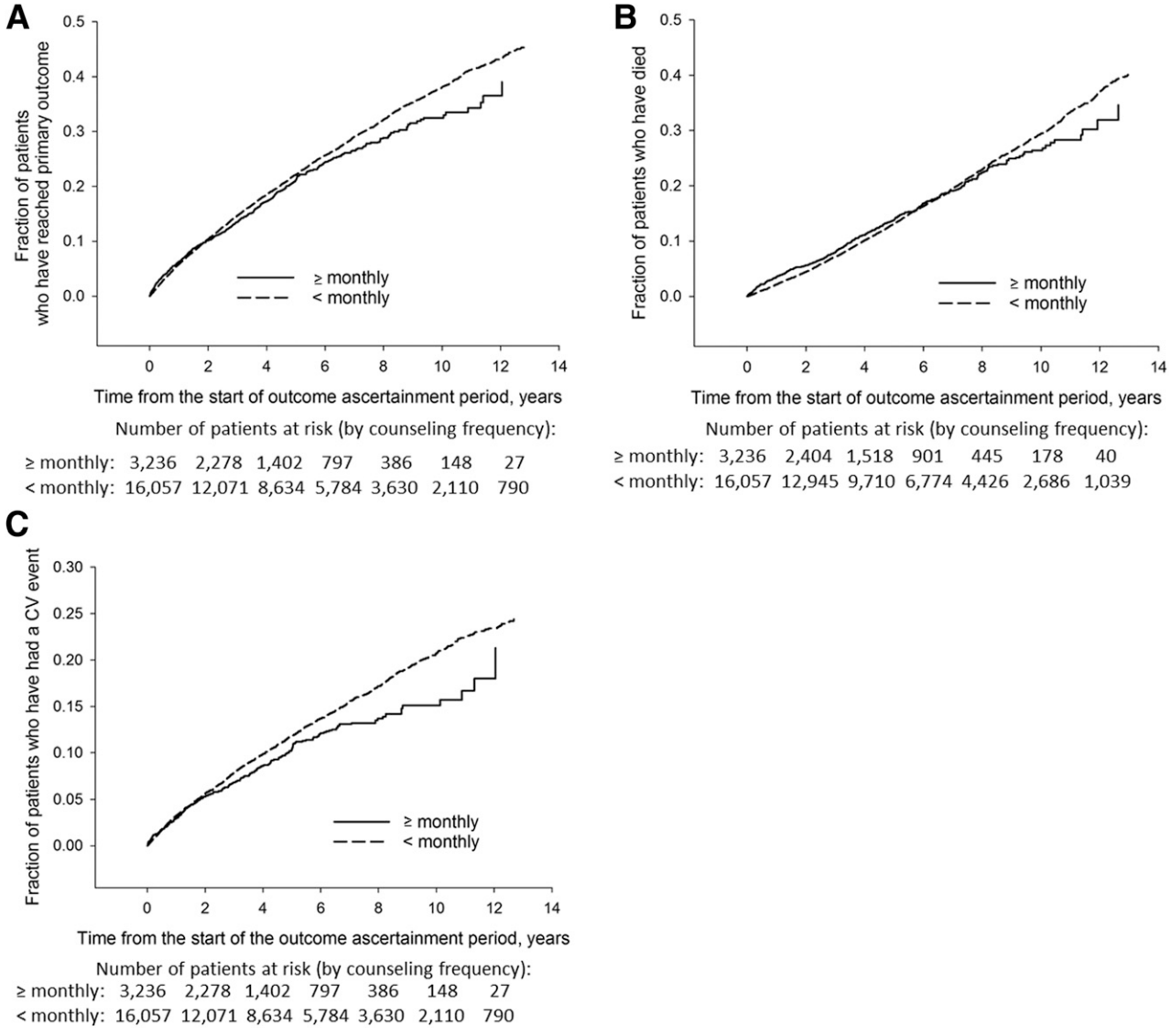

Figure 1—Time to study outcome by lifestyle counseling frequency category. *A*: Lifestyle counseling frequency and time to primary outcome. $P = 0.042$ (log-rank test). *B*: Lifestyle counseling and time to death. $P = 0.82$ (log-rank test). *C*: Lifestyle counseling and time to a cardiovascular (CV) event. $P = 0.0074$.

models were adjusted for patient demographics, comorbidities, and nonlifestyle management of diabetes during the treatment assessment period. We conducted a secondary analysis to determine whether the association between lifestyle counseling frequency and outcomes was mediated by changes in HbA_{1c} by adding time-weighted HbA_{1c} during the treatment assessment period as a covariate.

RESULTS

Study Cohort

Median baseline HbA_{1c} of 19,293 study patients was 7.8% (62 mmol/mol), and median frequency of lifestyle counseling during hyperglycemic periods was 0.46/month. Patients were followed for a mean of 5.4 years after the end of the treatment assessment period.

Univariable Analysis

The majority of patients (16,057) received lifestyle counseling less than monthly. During the 24-month treatment assessment period, HbA_{1c} decreased by 1.8% for patients with monthly or more versus 0.7% for less than monthly lifestyle counseling ($P < 0.0001$). Among patients with monthly or more lifestyle counseling (Fig. 1), the 10-year cumulative incidence rate of the primary outcome was 33.0% compared with 38.1% for less than monthly counseling ($P = 0.0005$).

Multivariable Analysis

In Cox multivariable analysis, frequency of lifestyle counseling (once per month vs. once per 3 months) was associated with hazard ratios for composite primary outcome, death, and cardiovascular events of 0.88 (95% CI 0.82–0.94; $P < 0.001$), 0.94 (0.86–1.01; $P = 0.101$), and 0.89 (0.82–0.97; $P = 0.006$), respectively. When time-weighted HbA_{1c} during the treatment assessment period was added to the model, the relationship between lifestyle counseling frequency and the primary outcome was no longer statistically significant.

CONCLUSIONS

In this large, real-world study, patients with diabetes who received more frequent lifestyle counseling from primary care providers were less likely to experience cardiovascular events or death. This relationship persisted after adjustment for other processes of diabetes care, including patient-provider encounters and intensification of diabetes medications. This finding was made possible by advances in both EMRs and technologies used to process EMR big data, including natural language processing.

As an observational analysis, this investigation does not provide direct evidence for a causal relationship and can only establish an association. However, mediation of the lifestyle counseling's association with clinical outcomes by changes in HbA_{1c} is consistent with our understanding of the pathophysiology of complications of diabetes and provides indirect support for causality (14).

A previously published large randomized clinical trial found that a lifestyle intervention did not reduce the incidence of cardiovascular events in patients with diabetes (15). However, there were several differences between the Look AHEAD (Action for Health in Diabetes) trial and our study that could explain this discrepancy. Participants in the Look AHEAD trial did not achieve a sustained blood glucose reduction; by year 2 of the 10-year intervention, the difference in HbA_{1c} between the two comparison groups narrowed to 0.3% and by year 4, to <0.2%. In contrast, in our study, the difference in HbA_{1c} between patients who received lifestyle counseling monthly or more versus less than monthly reached nearly 1%. Furthermore, this study included nearly four times as many patients as Look AHEAD, increasing its power to detect the effect of lifestyle counseling.

The current study found that to be effective, lifestyle counseling had to be intensive: Outcome benefits primarily accrued to patients who received lifestyle counseling monthly or more. This is consistent with our previous findings that intensive counseling is needed to achieve a significant improvement in glycemic control (11). This frequency of lifestyle counseling may not be universally feasible in routine care settings and may need to require different care models (e.g., group sessions, telemedicine) or be limited to selected individuals to be practical.

The results of this study should be interpreted in light of several limitations. We were unable to reliably distinguish between patients with type 1 and type 2 diabetes. The majority of patients in our study likely had type 2 diabetes; therefore, our findings may not be applicable to individuals with type 1 diabetes. Some episodes of lifestyle counseling may not have been reflected in providers' notes, while others may not have been picked up by the natural language processing software. If these omissions were distributed nonrandomly with respect to study outcomes, the findings may have been biased. Finally, because the study was limited to practices affiliated with academic medical centers in eastern Massachusetts, its findings may not be generalizable to other settings.

In summary, this study is the first to our knowledge to show that more frequent lifestyle counseling is associated with a decreased incidence of cardiovascular events and death in patients with uncontrolled diabetes. Further research is needed to confirm the causal nature of this relationship and to establish characteristics of lifestyle counseling that might have particularly strong effects on these important outcomes.

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