

Cholesterol Management of Patients With Diabetes in a Primary Care Practice–Based Research Network

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Objective: To determine the proportion of diabetic patients with and without coronary heart disease (CHD) who attained the American Diabetes Association recommended low-density lipoprotein cholesterol (LDL-C) target level of ≤ 2.60 mmol/L (≤ 100 mg/dL).

Study Design: Retrospective cross-sectional study.

Methods: Patients were identified by searching an electronic medical record database from March 1997 through March 2001. Search strategies included a problem list entry of diabetes mellitus or CHD, a medication in the antidiabetic or nitrate class, or a glycosylated hemoglobin value of $\geq 7.0\%$. Additional information included patient demographics, last LDL-C level, and use of a lipid-lowering agent.

Results: The study identified 10 201 patients (4844 with diabetes only, 1243 with diabetes plus CHD, and 4114 with CHD only). A greater proportion of patients who had diabetes and CHD attained the LDL-C target goal compared with patients who had diabetes only (32.1% vs 18.1%; $P < .001$). Furthermore, patients with diabetes plus CHD were more likely to have a LDL-C level measured within the past year (50.2% vs 42.5% respectively; $P < .001$). Multivariate logistic regression analysis revealed several factors associated with LDL-C goal attainment, including prior history of CHD, lipid-lowering therapy, tight glycemic control, HMO insurance, and a family medicine provider.

Conclusion: Although LDL-C goal attainment in patients with diabetes plus CHD was significantly better than that in patients with diabetes only, the prevalence of inadequate control in these high-risk populations is of national concern.

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An estimated 16 million people in the United States have diabetes mellitus. Diabetes is associated with a two- to fourfold increased risk of coronary heart disease (CHD).^{1,2} The risk of cardiovascular mortality in primary-prevention patients with diabetes is comparable to that of nondiabetic patients with known heart disease.^{3,4} Furthermore, patients with diabetes plus CHD experience a significantly higher rate of recurrent coronary events than patients who have CHD but do not have diabetes.

Lowering low-density lipoprotein cholesterol (LDL-C) levels has been shown to decrease cardiovascular risk in primary-prevention and secondary-prevention patients.⁵⁻¹³ Subgroup analyses of lipid-lowering trials further demonstrate that patients with diabetes plus CHD derive greater benefit from LDL-C-lowering than similar

CHD patients without diabetes.^{8,12,14} In the Scandinavian Simvastatin Survival Study, which enrolled CHD patients, all patients derived benefit from lipid lowering.¹⁴ However, the absolute 6-year benefit for patients with diabetes or impaired fasting glucose tolerance was greater than that for those with normal fasting glucose tolerance. Similar observations were made in another secondary-prevention lipid-lowering study, the Cholesterol and Recurrent Events Trial.¹² Patients with diabetes had higher rates of coronary events and a greater absolute risk reduction compared with patients without diabetes. Likewise, primary-prevention patients with diabetes in the Air Force/Texas Coronary Atherosclerosis Prevention Study experienced a greater benefit from lipid-lowering therapy than patients without diabetes.⁶ Data from these large, randomized controlled trials provide the rationale for aggressively lowering LDL-C levels in all patients with diabetes.

In 1998, the American Diabetes Association (ADA) first published clinical practice guidelines advocating a goal LDL-C level of ≤ 2.6 mmol/L (≤ 100 mg/dL) for all patients with type 2 diabetes.¹⁵ In May 2001, the updated National Cholesterol Education Program guidelines (Adult Treatment Panel III [ATP III]) included diabetes as a cardiac risk equivalent and lowered the LDL-C goal for all patients with diabetes to 2.6 mmol/L.¹⁶ This target is now equivalent to the LDL-C goal for patients with known coronary heart disease first recommended in the 1993 ATP II guidelines.¹⁷ Despite these 1993 recom-

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mentations, previous reports have shown poor attainment of LDL-C targets (range 23.3%-39%) in the CHD population in a variety of healthcare settings.¹⁸⁻³¹ Less is known about cholesterol management for patients with diabetes, particularly in the community-based primary care setting. The primary purpose of this study was to determine LDL-C goal attainment for all patients with diabetes in a large community-based primary care setting. Secondary objectives included identifying factors that may correlate with LDL-C goal attainment or prescription of lipid-lowering drugs, as well as determining whether diabetic patients differ from nondiabetic patients who have CHD with respect to goal attainment.

RESEARCH DESIGN AND METHODS

Study Site

This cross-sectional study was approved by the Providence Health System institutional review board and was conducted in the Providence Primary Care Practice-Based Research Network (PBRN). At the time of the study, the Providence Primary Care PBRN consisted of 80 practitioners providing care to more than 200 000 patients in 9 clinic locations in Portland, Ore. The practices share a common electronic medical record (EMR). Problem lists are generated and maintained through physician entry of patient diagnosis, analogous to the traditional paper chart. Problem list entries are stored in a searchable format, based on the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* system. All office encounters and telephone contact by all physicians and staff are documented in text-based format. Additionally, patient data—including demographics, insurance status, and medications—are available. Laboratory values are interfaced in the EMR through a centralized laboratory. No in-office laboratory testing relevant to the study is performed in Providence Primary Care PBRN clinics.

Subjects

This study included all diabetic patients in the Providence Primary Care PBRN as of March 23, 2001, stratified by the presence or absence of CHD. Coronary heart disease was defined as a history of myocardial infarction, ischemic heart disease, angina pectoris, or surgical history of either coronary artery bypass grafting or percutaneous transluminal coronary angioplasty. For comparison, patients with CHD and no diagnosis of diabetes also were included. Patients were excluded if they were younger than 18 years of age, or if their chart had been inactivated because of their death or departure

from the medical group. Patients also were excluded if their primary care provider had left the medical group before March 2001.

Problem and medication list data, as well as laboratory values, were searched by a query of the EMR database, Logician™ version 5.4 (GE Medical Systems, Waukesha, Wis). Patients with diabetes were identified by the *ICD-9-CM* diagnosis codes 250.00 through 250.99. To compensate for incomplete problem lists, additional patients with diabetes were sought through an EMR query of active medications and laboratory values. Patients were included in the diabetes analyses if they were prescribed an antidiabetic agent or had any glycosylated hemoglobin (HbA_{1c}) value of $\geq 7.0\%$. CHD patients were identified using the *ICD-9-CM* diagnosis codes 410.x-414.x, 429.2, 429.7, 429.79, 440.x, V45.81, V45.82, and V81.0. Patients with an active prescription for any nitrate product also were identified as having CHD.

Other Data Collected

Once the study population was identified, demographic data, presence of hypertension diagnosis on the EMR problem list (*ICD-9* codes 401.00-401.99), most recent HbA_{1c} measurement, and selected characteristics of the primary care physician were collected. The most recent LDL-C value in the previous 3 years (March 1997 to March 2001) also was extracted by EMR query. Data on the prescribing of lipid-lowering agents were determined by an EMR query for active medications.

Analysis

Patients were considered to be at LDL-C goal if their most recent LDL-C value was ≤ 2.6 mmol/L. A patient without a LDL-C value in the 3-year period was considered not to be at goal. We analyzed all patients in 3 groups: diabetes only, diabetes plus CHD, and CHD only. Continuous variables were described by means and standard deviations and were compared by 1-way analysis of variance with post-hoc comparison using the Scheffe test. Categorical data were described by percentages and compared by using the chi-square test with a continuity correction. Univariate analyses were performed to identify factors significantly associated with an increased likelihood of LDL-C goal attainment and prescription of lipid-lowering drugs. Results of the univariate analyses were verified by multivariate logistic regression analyses. Factors analyzed included age, sex, disease state(s), presence of lipid-lowering drug, insurance type, HbA_{1c} measurement, and primary care physician specialty (family medicine or internal medicine). Second- and third-order interactions between age, sex, disease state, and hypertension also were assessed. A *P* value

less than 0.05 was considered significant. All statistical analyses were performed using SPSS version 10.0.5 for Windows (SPSS Inc, Chicago, Ill).

RESULTS

Patient Population

Of the 210 000 active charts, 10 201 patients met inclusion and exclusion criteria (6087 patients with diabetes and 5357 patients with CHD). Of these patients, 4844 had diabetes only, 1243 had diabetes plus CHD, and 4114 had CHD only. Of the total diabetic population, 91.4% were identified by problem list entry, and the remaining 6.2% and 2.4% were identified by a HbA_{1c} measurement of >7.0% and antidiabetic medication use, respectively. In the CHD population, 80.4% were identified by problem list entry and 19.6% were identified by a nitrate prescription.

Patient Characteristics

The study population is characterized in detail in **Table 1**. Of note, all CHD patients were significantly older and more likely to be male than patients with diabetes only. Patients with diabetes plus CHD had a significantly higher prevalence of hypertension than patients with either diabetes only or CHD only (55.1%, 46.2%, and 43.4%; *P* < .001). Patients with diabetes plus CHD also were more likely to have an active prescription for a lipid-lowering drug (*P* < .001). In patients with diabetes, the mean HbA_{1c} value was significantly lower in the population with CHD compared with the population without CHD (7.2% vs 7.4%; *P* < .001).

LDL-C Goal Attainment

Only 22% of the 10 201 patients achieved goal LDL-C. Goal attainment was highest among patients with diabetes plus CHD compared with patients who had diabetes only or CHD only (32.1%, 18.1%, and 23.8%, respectively; *P* < .001). **Figure 1** illustrates the similar distributions among the 3 subgroups. The mean LDL-C level for the diabetes plus CHD population was lower than that for diabetes-only population or the CHD-only population (2.68 mmol/L [103.7 mg/dL], 3.04 mmol/L [117.5 mg/dL], and 2.88 mmol/L [111.4 mg/dL], respectively; *P* < .001).

Of the 3181 patients with an active prescription for a lipid-lowering drug, 38.6% had a measured LDL-C value that was at goal. Patients with diabetes only who were taking a lipid-lowering drug were less likely to attain LDL-C goal than those with diabetes plus CHD or CHD only (33.2%, 41.5%, and 40.6%; *P* < .001). Of the 7020 patients managed without lipid-lowering drugs, 14.7% achieved LDL-C goal. In the absence of pharmacotherapy, patients with diabetes plus CHD had a higher LDL-C-goal attainment rate than patients with diabetes only or CHD only (23.8%, 14.6%, and 12.3%, respectively; *P* < .001).

Cholesterol Monitoring

A total of 4409 patients (43.2%) had a LDL-C measurement in the prior 12 months (March 23, 2000, to March 23, 2001), whereas 4011 patients (39.3%) had no chart evidence of a LDL-C measurement in the prior 3 years (**Figure 2**). Patients with diabetes plus CHD were monitored more frequently in the past year than patients with diabetes only or CHD only (50.2%, 42.5%, and 41.9%

Table 1. Population Demographics*

Characteristic	Diabetes Only (n = 4844)	Diabetes plus CHD (n = 1243)	CHD Only (n = 4114)
Mean (SD) age, y	61.1 (15.5)	72 (10.4) [†]	72.7 (12.6) [†]
No. (%) males	2100 (43.4)	630 (50.7) [†]	2195 (53.4) [†]
No. (%) with concurrent hypertension	2239 (46.2) [‡]	685 (55.1)	1784 (43.4) [‡]
Mean (SD) current HbA _{1c} value	7.38% (1.74%)	7.24% (1.51%)	
Mean (SD) recent LDL-C value	117.5 (32.9) [‡]	103.7 (32.8)	111.4 (32.2) [‡]
Insurance			
Commercial HMO	1664 (34.4)	503 (40.5)	1489 (36.2)
HMO Medicare	664 (13.7)	295 (23.7)	962 (23.4)
Fee for service	1846 (38.1)	174 (14)	745 (18.1)
Medicare	508 (10.5)	247 (19.9)	818 (19.9)
Uninsured	148 (3.1)	20 (1.6)	82 (2.0)
Medicaid	14 (0.3)	4 (0.3)	18 (0.4)

*CHD indicates coronary heart disease; HbA_{1c}, glycosylated hemoglobin; LDL-C, low-density lipoprotein cholesterol.

[†]Compared with patients who had diabetes only; *P* < .001.

[‡]Compared with patients who had diabetes plus CHD; *P* < .001.

respectively; $P < .001$). The LDL-C monitoring rates for all pharmacotherapy-managed patients were significantly higher than those for those patients not prescribed lipid-lowering medication.

Pharmacotherapy

Of 10 201 patients, 31.2% had an active prescription for a lipid-lowering drug. When comparing patients who had diabetes plus CHD with patients who had diabetes only, several factors were significantly associated with lipid-lowering pharmacotherapy. These included younger age (odds ratio [OR] 0.99; $P = .005$), male sex (OR 1.21; $P = .003$), diabetes plus CHD (OR 3.58; $P < .001$), comorbid hypertension (OR 1.76; $P < .001$), and HMO insurance (OR 2.27 and $P < .001$ for HMO vs uninsured; OR 1.27 and $P = .002$ for HMO vs fee for service [FFS] or Medicaid). Prescribing was lower in uninsured, FFS, and Medicaid insurance categories compared with HMO and Medicare categories (Table 2). Most patients received monotherapy with a 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitor (statin). The second-most-utilized class of medications in the diabetic population was fibric acid derivatives, followed by niacin, then bile acid sequestrants. In the population of CHD-only patients, niacin was prescribed more commonly than a fibrate or bile acid sequestrant (Table 3).

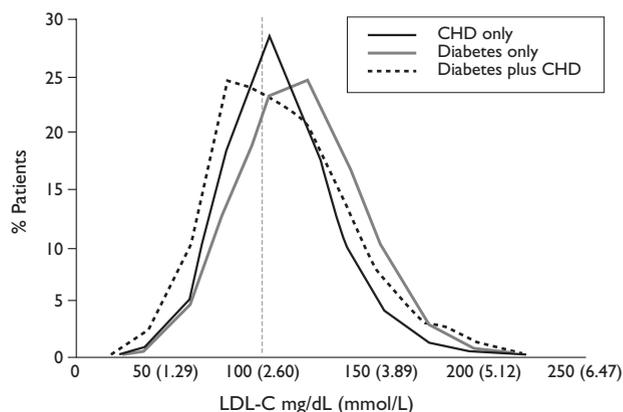
Multivariate Analysis

Logistic regression demonstrated that several patient characteristics were significantly related to LDL-C goal attainment when comparing patients who had diabetes plus CHD with patients who had diabetes only. Diabetes plus CHD (OR 1.46), lipid-lowering therapy prescription (OR 2.43), tighter glycemic control (OR 1.15) (all $P < .001$), HMO insurance (OR 1.28 vs FFS or Medicaid and OR 1.29 vs Medicare; $P < .01$), and a provider with a specialty in family medicine (OR 1.24; $P = .007$) correlated with an increased likelihood of LDL-C goal attainment. The interacting variables that also correlated with improved LDL-C goal attainment included male sex, increasing age, and concurrent diabetes plus CHD.

DISCUSSION

Up to three fourths of mortality among diabetic patients can be attributed to atherosclerotic disease.¹ A recent meta-analysis of randomized, controlled trials evaluated the relative benefit of intense management of LDL-C, blood pressure, and hyperglycemia on cardiovascular outcomes in patients with diabetes mellitus.³²

Figure 1. Distribution of the Most Recent LDL-C Values, Collected from 1997 to 2001

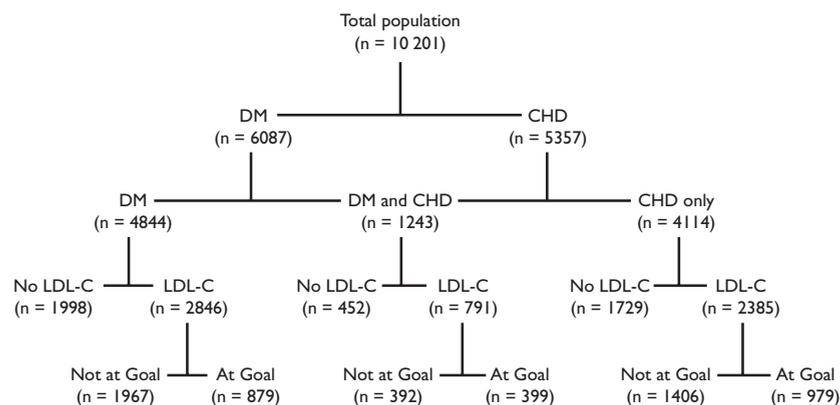


Levels at goal are to the left of the dividing line; levels above goal are to the right. CHD indicates coronary heart disease; LDL-C, low-density lipoprotein cholesterol.

The results of this meta-analysis demonstrate that lipid lowering and blood pressure management in patients with diabetes are associated with significantly greater cardiovascular benefit compared with glycemic control. These results, and subgroup analysis from landmark cardiovascular trials, imply the paramount importance of cholesterol management in the care of patients with diabetes, reinforcing ADA guidelines.^{6,8,12,14} The publication of the ATP III guidelines, 2 months after our data were collected, help support aggressive lipid control in this high-risk population.

Although LDL-C goal attainment has been reported in the CHD population in several diverse healthcare environments,¹⁸⁻³¹ goal attainment in patients with diabetes is less well characterized.^{32,33} Our study reports a poor rate of LDL-C goal attainment for a large population of patients with diabetes in a community-based primary care setting. Although ADA guidelines advocate identical LDL-C targets, the goal attainment rate for patients with diabetes only was significantly lower than that for patients with diabetes plus CHD.^{15,17} Inexplicably, patients with diabetes plus CHD achieved the target LDL-C goal significantly more often than patients with diabetes only or patients with CHD only. This pattern of best outcomes for patients with diabetes plus CHD was consistent for mean LDL-C level, LDL-C monitoring frequency, and use of lipid-lowering therapy.

These results are comparable to those in a previously published report on LDL-C goal attainment in members of a staff-model managed care organization.³³ Our study is of additional interest as it represents a mix of insurance payers, with and without pharmacy benefits, along with uninsured patients. Furthermore, patients

Figure 2. LDL-C Goal Attainment in Patients with Diabetes and/or CHD

CHD indicates coronary heart disease; DM, diabetes mellitus; LDL-C, low-density lipoprotein cholesterol.

were identified based on data from the medical chart, and information about lipid-lowering medications was abstracted from chart medication lists, not claims data. As such, our data describing the presence and type of lipid-lowering therapy may more closely represent physician intent, but the data are limited in their characterization of patient compliance and adherence. Despite differences in geography, healthcare environment, and sources of data, the findings are consistent.

Results of another study describing cardiovascular risk factor management in the diabetic population were recently reported.³⁴ Although LDL-C goal attainment reached 35.5%, several factors limit the applicability of these results to the community-based population. First, the study design defines active patients as those with a visit in the prior year. This design might select for a population of patients more engaged in their care, and their goal attainment rates may not be generalizable to the entire population of patients with diabetes. An additional limitation is the university and Veterans Affairs setting. Although the findings are important, the patient population and care processes differ from those in community-based healthcare, and relevance to a wider population cannot be assumed.

Although our study characterizes LDL-C management outcomes as poor, it sheds little light on the underlying barriers to better results. Data from medication lists reveal that only 20% of the total diabetic population received a prescription for lipid-lowering therapy. Moreover, of those patients on lipid-lowering therapy, 85% were receiving statin monotherapy, while only 5.7% received more than monotherapy. Accordingly, the low utilization of pharmacotherapy implies that suboptimal goal attainment is not predominantly due to inadequate response to maximal therapy.

This study likewise provides no definitive explanation for the consistent pattern of best goal attainment in patients with diabetes plus CHD. LDL-C monitoring frequency and prescribing of lipid-lowering therapy may be considered markers for aggressive management. The reported frequencies of monitoring and drug therapy for patients with diabetes plus CHD compared with the other 2 groups further suggest better management of this population. These results may point to greater provider attentiveness to LDL-C status in this category of patients, who are at highest risk. Additionally,

heightened awareness on the part of patients with concurrent diabetes plus CHD may contribute to superior LDL-C goal attainment. Further investigation to elucidate and overcome the barriers is warranted.

The chief limitation of this study is the undefined frequency of incomplete problem and medication lists. Incomplete problem lists could result in only partial identification of the diabetic population and inaccurate definition of primary-prevention and secondary-prevention subgroups. This limitation was partially addressed through an identification methodology that incorporates medication and laboratory markers for the relevant diagnoses. Medication list errors should affect primarily the pharmacotherapy analysis. This type of error may cause an overestimate of the use of lipid-lowering agents, rather than an underestimate, because the predominant source of error is the inclusion of discontinued medications. Another limitation is the lack of standardized documentation for diet, exercise, and weight loss. It is assumed that all Providence Primary Care PBRN patients with CHD or diabetes receive instruction on lifestyle management regardless of prescribed lipid-lowering medications.

It is likely that some of the EMR laboratory data are incomplete, based on some limited use of laboratories outside the delivery system. Although established office work flow patterns suggest this incidence is low, laboratory results based on blood drawn during inpatient stays also often are not incorporated into the EMR database. Because primary care physicians would not be aware of the missing laboratory results, they not incorporated in patient management. Therefore, it seems unlikely that missing laboratory values would contribute significantly to goal attainment rates.

The strengths of this study include the wide applicability of these data to community-based, private-prac-

Table 2. Effect of Insurance Type on LDL-C Goal Attainment and Prescription of a Lipid-Lowering Drug*

Insurance Type	No. (%) of Patients		
	DM Only	DM plus CHD	CHD Only
LDL-C Goal Attainment			
HMO	495/2328 (21.3)	280/798 (35.1)	600/2451 (24.5)
Medicare	86/508 (16.9) [†]	69/247 (27.9) [†]	184/818 (22.5) [†]
Fee for service	278/1846 (15.1) [§]	48/174 (27.6)	190/745 (25.5) [‡]
Uninsured	18/148 (12.2) [†]	2/20 (10) [†]	3/82 (3.7) [§]
Medicaid	2/14 (14.3)	0/4 (0)	2/18 (11.1)
Lipid-Lowering Drug Prescribed			
HMO	471/2328 (20.2)	386/798 (48.4)	978/2451 (39.9)
Medicare	124/508 (24.4) ^{†,‡}	108/247 (43.7)	309/818 (37.8)
Fee for service	320/1846 (17.3) ^{†, , †}	82/174 (47.1)	356/745 (47.8) ^{‡,§, †}
Uninsured	15/148 (10.1) [†]	6/20 (30)	19/82 (23.2) [†]
Medicaid	1/14 (7.1)	1/4 (25)	5/18 (27.8)

*CHD indicates coronary heart disease; DM, diabetes mellitus; LDL-C, low-density lipoprotein cholesterol.

[†]P < .05 vs HMO.

[‡]P < .001 vs uninsured.

[§]P < .001 vs HMO.

^{||}P < .05 vs uninsured.

^{††}P < .001 vs Medicare.

Table 3. Types of Lipid-Lowering Drugs Prescribed*

Lipid-Lowering Drug	No. (%)			
	Total Population (n = 3181)	DM Only (n = 931)	DM and CHD (n = 583)	CHD Only (n = 1667)
Statin	2748 (86.4)	782 (84)	505 (86.6)	1461 (87.6)
Fibrate	114 (3.6)	69 (7.4)	24 (4.1)	21 (1.3)
Niacin	92 (2.9)	25 (2.7)	9 (1.5)	58 (3.5)
Bile acid sequestrant	26 (0.8)	11 (1.2)	2 (0.3)	13 (0.8)
More than 1 lipid-lowering drug	201 (6.1)	44 (4.7)	43 (7.4)	114 (6.8)

*CHD indicates coronary heart disease; DM, diabetes mellitus.

Results may not add to 100% since a patient may be on multiple therapies.

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 tice providers in urban and suburban settings. All data were collected from the medical charts used in practice rather than insurance claims. Claims data have demonstrated questionable reliability in identifying prognostically important conditions.³⁵ The goal attainment seen in our CHD population, which is similar to that reported in previous publications, further supports the applicability of these results.

CONCLUSION

In conclusion, LDL-C goal attainment in high-risk

patients with diabetes and/or CHD was disappointing. Although the highest risk patients, those with both diabetes and known CHD, are more closely managed and have better LDL-C goal attainment, their outcomes still must be considered suboptimal. The barriers to successful lipid management of patients with diabetes are inadequately defined, and further investigation is warranted. The observation that patients who have diabetes plus CHD receive more aggressive management and have better goal attainment compared with patients who have diabetes or CHD alone is likewise unexplained.

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