Risk of Coronary Artery Disease in Type 2 Diabetes and the Delivery of Care Consistent With the Chronic Care Model in Primary Care Settings

A STARNet Study

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Background: Modifiable risks for coronary heart disease (CHD) in type 2 diabetes include glucose, blood pressure, lipid control, and smoking. The chronic care model (CCM) provides an organizational framework for improving these outcomes.

Objective: To examine the relationship between CHD risk attributable to modifiable risk factors among patients with type 2 diabetes and whether care delivered in primary care settings is consistent with the CCM.

Subjects/Methods: Approximately 30 patients in each of 20 primary care clinics. CHD risk factors were assessed by patient survey and chart abstraction. Absolute 10-year CHD risk was calculated using the UK Prospective Diabetes Study risk engine. Attributable risk was calculated by setting all 4 modifiable risk factors to guideline indicated values, recalculating the risk, and subtracting it from the absolute risk. In each clinic, the consistency of care with the CCM was evaluated using the Assessment of Chronic Illness Care (ACIC) survey.

Results: Only 15.4% had guideline-recommended control of A1c, blood pressure, and lipids. The absolute 10-year risk CHD was 16.2% (SD 16.6). One-third of this risk, 5.0% (SD 7.4), was attributable to poor risk factor control. After controlling for patient and clinic characteristics, the ACIC score was inversely associated with attributable risk: a 1 point increase in the ACIC score was associated with a 16% (95% CI, 5–26%) relative decrease in attributable risk.

Discussion: The degree to which care delivered in a primary care clinic conforms to the CCM is an important predictor of the 10-year risk of CHD among patients with type 2 diabetes.

Key Words: primary care, type 2 diabetes, chronic disease, myocardial infarction, organization of care

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People with type 2 diabetes are at considerable risk of excessive morbidity and mortality from coronary heart disease (CHD).[1] Although there has been a decline in the rate of incident CHD events among adults with diabetes, the absolute risk of CHD is 2-times higher than among patients without diabetes.[2] Multiple risk factors for CHD among patients with type 2 diabetes have been identified including control of glucose, blood pressure (BP), and lipids, as well as smoking status.[3] Additional risk factors for CHD include age, race/ethnicity, duration of diabetes, and gender. These latter factors may be considered fixed, although the former risk factors are potentially modifiable.

Current clinical practice guidelines recommend the following target levels for potentially modifiable risk factors: A1c $\leq$7.0 mg%; BP $\leq$130/80 mm Hg; and low-density lipoprotein cholesterol $\leq$100 mg/dL (if no documented heart disease).[4] Despite wide dissemination of evidence-based guidelines and the availability of new therapeutic classes of medications, there has been little improvement in CHD risk factors, specifically A1c and BP control, and only small improvements in lipid control among people with type 2 diabetes over the past decade.[5] Thus, a wide gap exists between established evidence for control of these risk factors and what is actually achieved in the setting where most patients with type 2 diabetes receive their diabetes care: the primary care clinic.

Several approaches to improving the care of patients with a chronic illness have been developed including, most notably, the chronic care model (CCM). The CCM suggests that the presence of 6 specific organizational characteristics should result in improvements in outcomes for patients with

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chronic illness: organizational support, community linkages, self-management support, decision support, delivery system design, and clinical information systems.[6,7] Prior studies have shown that the presence of these characteristics is associated with process quality of care measures,[8] such as the frequency of measuring glycosolated hemoglobin, BP, or referrals for eye exams. The purpose of this study is to examine the relationship between whether care delivered in primary care settings is consistent with the CCM and the 10-year risk of fatal or nonfatal CHD attributable to poor control of modifiable CHD risk factors among patients with type 2 diabetes.

METHODS

Setting and Sample Selection

A full description of the study has been published elsewhere.[9] Briefly, 20 primary care clinics within the South Texas Ambulatory Research Network (STARNet) were recruited in a snowball method with an attempt to identify and recruit primary care settings where people with type 2 diabetes are mostly likely to seek care. These settings included solo practice physician clinics (n = 11; physicians = 11), group practice settings (n = 3; physicians = 10), community health centers (n = 1; physicians = 1), VA primary care clinics (n = 2; physicians = 11), and city-county health clinics for uninsured patients (n = 3; physicians = 12). Within each clinic site, a minimum of 30 consecutive patients presenting with an established diagnosis of type 2 diabetes were recruited to participate in the study by a trained research assistant. Every patient presenting in each clinic with an established diagnosis of type 2 diabetes was recruited until at least 30 subjects were enrolled. This required an average of 2–3 weeks in each clinic. For all 30 patients, information was collected by an exit survey administered after the physician visit and by abstraction of their medical record. Age, duration of diabetes, smoking status, and race/ethnicity were collected with the survey. Data collected on chart audit included comorbid conditions, and the most recent values of A1c, BP, and lipid levels.

Because we were primarily interested in the relationship between patient exposure to the CCM and risk of CHD, we limited our analytic sample to patients whose diabetes had been managed in the clinic for at least 1 year. In addition, we limited our sample to those with diagnosis of diabetes for at least 1 year and patients with no prior history of CHD disease. This later restriction was designed to conform to the methodology used in creating the UK Prospective Diabetes Study (UKPDS) risk engine and replicates efforts in another recent study.[10]

CHD Risk Factors

Four potentially modifiable risk factors for CHD were examined: A1c, BP, lipid levels, and smoking status. Standards for control of cardiovascular risk factors were based on the 2002 American Diabetes Association Clinical Practice.[11] These recommendations were chosen because they were published before data collection began and represented the most current guidelines for community physicians at that time (A1c $\leq$7.0; BP $\leq$130/80; high-density lipoprotein (HDL) cholesterol $\geq$45; smoking status: no).

Calculation of 10-Year Risk of CHD

The 10-year absolute risk of fatal and nonfatal CHD were estimated for each patient using the UKPDS risk engine version 2.0.[12] The values obtained from UKPDS risk engine are based on weightings of fixed risk factors: age, duration of diabetes, sex, ethnicity, and the presence of atrial fibrillation, and modifiable risk factors: A1c, systolic BP, total cholesterol, HDL cholesterol, and smoking status.

Two different UKPDS risk calculations are reported: (1) the absolute risk of developing fatal or nonfatal CHD over the subsequent 10-years using current values of all of the above factors; (2) the attributable risk, ie, the excess risk that is due to poor control of potentially modifiable risk factors. The attributable risk was calculated by setting each patient level risk factor at the then current guideline recommended maximum level if it was above that level: ie, A1c = 7.0 if A1c >7; BP = 130/80 if BP >130/80; HDL cholesterol = 45 if HDL cholesterol <45; and smoking status = "no" if patient is a current smoker, and then recalculating the UKPDS risk score. The difference between this new score and the absolute risk is reported as the attributable risk, that is, the amount of risk attributable to the 4 modifiable risk factors. All risk values are stated as percents.

CCM and Clinic Structure

The degree to which care in each clinic was consistent with the CCM was measured with the Assessment of Chronic Illness Care (ACIC) survey, completed by all clinicians in each clinic.[13] The ACIC is a 25 item survey that measures the presence of the elements of the CCM. Each item is scored on a 0–11 scale and provides subscale scores for each of the 6 CCM components as well as a total score. The presentation of the scales on the instrument were such that scores from 0 to 2 represent "limited support," 3 to 5 represent "basic support," 6 to 8 is "good support," and 9 to 11 represent "fully developed support." The utility of the instrument to evaluate how care delivery systems are consistent with the CCM is supported by the findings of a study of an intervention for diabetes and congestive heart failure: all 6 subscales were responsive to process of care improvement. In addition, in the recent Institute for Healthcare Improvement chronic care collaborative intervention, changes in the total ACIC score were associated with the depth of organizational change activities in each clinic.[14] Thus, not only is the instrument sensitive to organizational change, but this change is also associated with observed improvement efforts and changes in chronic disease quality of care indicators. The mean value of the total score across all clinicians within each clinic was used in this study as a measure of the degree to which the care delivered was consistent with the CCM.

The degree to which care delivered conforms to the CCM is just one dimension of clinic structure. Two other potentially important structural characteristics were also included in the analysis: the size of the clinic and the presence of an electronic medical record (EMR). Larger clinics often have more resources to support chronic illness care such as

health educators. Clinics with an EMR are often able to carry out activities such as generating chronic disease performance reports for feedback to clinicians who compare them with their peers in an effort to improve performance.[15] Clinic size was defined as "small" if there were 1-2 physicians in the clinic and "large" if there were more than 2 physicians. The presence of an EMR was also noted. An EMR was defined as "present" if there was a computerized system that: (1) allowed for entry of patient chart notes during or after a visit; (2) was interoperable with outside systems such as allowing for transfer of laboratory data; and (3) linked functions such as scheduling or billing.

Analysis

Descriptive statistics (means, SD, percentages) were generated for patients and clinics. Ordinary least squares is not appropriate to analyze dependent variables that always take on the value of zero or higher, for example CHD risk, because it can lead to negative predictive values. Instead, the relationship between clinic size, the use of an EMR, ACIC score, and CHD risk was analyzed with a Poisson model with a hierarchical approach to account for the clustering of patients within clinics. The Poisson approach was chosen because it is consistent with the both the distribution and the nature of dependent variable, as it is a function of events, the number if subjects who develop cardiac heart disease over a 10-year period. The only explanatory variable at the patient level was the number of chronic diseases recorded in the patients chart as a measure of case-mix. Although it is possible to use a more sophisticated approach, the literature supports the use of counts of chronic diseases to control for confounding in ambulatory care settings.[16,17] In addition, number of coexisting conditions may be an important patient characteristic not captured in the absolute UKPDS score. For example, attention to other conditions may impair the ability of the patient and clinician to achieve good control of modifiable risk factors. For absolute risk, no other explanatory variables were entered at the patient level because patient characteristics such as age, sex, and race/ethnicity were used to calculate the dependent variable: the UKPDS risk score. However, because the attributable risk only reflects the amount of risk from the modifiable risk factors, patient demographics were included in model for attributable risk.

Separate hierarchical Poisson models were run for each type of risk: absolute and attributable risk. Results are reported as event rate ratios, that is, the ratio of the risk for one group compared with another group. For example, the ratio of attributable risk in a clinic with an ACIC score of 6 over the attributable risk for a clinic with a score of 7. If one subtracts this value from 1, the resulting number is the relative percent change in attributable risk for a 1 point increase in ACIC score. Descriptive statistics were run in SPSS (version 13.0, SPSS, Inc., 2003, Chicago, IL). The hierarchical Poisson models were conducted in HLM version 6.0.[18] This study was reviewed and approved by the Institutional Review Board at the University of Texas Health Science Center, San Antonio, Texas.

RESULTS

All patients who were approached agreed to participate in the study. A total of 617 patients were enrolled across 20 primary care settings. Of those individuals, 424 met the following inclusion criteria: (1) they had a diagnosis of diabetes for more than 1 year; (2) they had been with their current physician for at least 1 year; and (3) they had no previous diagnosis of coronary artery disease. Of these, 313 (74%) had complete data to calculate a 10-year risk of CHD using the UKDPS risk engine, representing the final analytic sample for this study.

Characteristics of the patients and clinics are shown in Table 1. The majority were Hispanic, females, and over the age of 58. Approximately half of the patients had adequate control of each risk factor. Of note is the finding that only 15.4% of patients had all 3 risk factors at current evidence-based recommended target levels and 17.3% had none of the 3 risk factors at target levels. The response rate for the ACIC survey was 100%. The mean ACIC score across the 20 clinics was 6.34 (SD, 1.76; range, 3.32–9.60; median, 6.48, interquartile range, 5.52–7.64) out of a possible range from 0 to 11. The distribution of clinics across the 4 anchor statements described above for the 6 components of the CCM are shown in Table 2. The element of the CCM least likely to be present was clinical information systems, although self-management support and delivery system design were most likely to be consistent with the CCM, followed closely by organizational support and decision support.

The 10-year risk of developing CHD is also shown in Table 1. When these values are averaged by clinic, the clinic with the lowest mean absolute risk was 7.4 times higher in the

TABLE 1. Patient and Clinic Characteristics (n = 313)

Patients	Mean (SD) or Percent (%)
Age (mean, SD)	58.9 yr (SD 11.8)
Female	54.6%
Hispanic	55.2%
High school graduate or above	70.8%
Married	70.2%
No. chronic diseases	4.9 (2.3)
CV risk factors	
HbA1c ≤7.0	43.3%
BP ≤130/80	48.5%
LDL ≤100	50.0%
Number of risk factors at target	
None	17.3%
One	36.2%
Two	31.2%
All three	15.4%
10-yr CHD risk (UKPDS)	
Absolute risk	16.2% (16.6)
Attributable risk	5.0% (7.4)
Clinics	
ACIC score	6.3 (1.8)
Small clinic (≤2 physicians)	50%
EMR (yes)	30%

TABLE 2. Elements of the Chronic Care Model Present (Number of Clinics in Each Category, n = 20 Clinics)

	Limited (Score 0–2)	Basic (Score 3–5)	Good (Score 6–8)	Full (Score 9–11)
Organization support Mean (SD) 6.9 (2.1)	1	4	10	5
Community linkages Mean (SD) 7.6 (2.6)	1	6	3	10
Self-management support Mean (SD) 7.6 (2.6)	0	4	10	6
Decision support Mean (SD) 6.9 (2.3)	0	5	9	6
Delivery system design Mean (SD) 6.5 (1.8)	0	4	13	3
Clinical information systems Mean (SD) 3.8 (1.9)	4	12	4	0
Total score Mean (SD) 6.3 (1.8)	0	4	14	2

clinic with the highest compared with the clinic with the lowest (range, 0.065–0.485). For the attributable risk there was a 10-fold difference between the clinic with the lowest attributable risk (0.015) and the one with the highest (0.156). Across all clinics, the excess risk of CHD due to poorly controlled risk factors was 5%. That is, if all modifiable risk factors were well controlled, the absolute risk of CHD would drop from 16.2% to 11.2%, or a 31% relative decrease.

The results of the hierarchical models are shown in Table 3. Older subjects, male subjects and Hispanic subjects had higher attributable risk. Attributable risk but not absolute risk, was inversely associated with the ACIC score. As the ACIC score increased, the level of attributable risk decreased. For a 1 point increase in the ACIC score, there was a 16% (95% CI, 5%–26%) relative decrease in attributable risk, from 5.0% to 4.2%, for example. We also ran a multivariable linear regression model and a model with a log transformation of the dependent variables and found that the ACIC score was significantly associated with attributable risk, but not absolute risk, in each of those models in the same direction as that in the reported Poisson model (data not shown).

TABLE 3. Predictors of 10-yr CHD Risk from Hierarchical Poisson Models

	Event Rate Ratio	95% CI
Absolute risk		
Number of diagnoses	1.03	0.96–1.10
EMR	1.75	1.08–2.88
Small clinic	0.70	0.49–0.99
ACIC score	0.88	0.78–1.00
Attributable risk		
Age	1.03	1.02–1.04
Male	1.78	1.24–2.57
Hispanic	1.97	1.34–2.92
Number of diagnoses	0.94	0.87–1.03
EMR	1.74	1.17–2.59
Small clinic	0.76	0.53–1.10
ACIC score	0.84	0.74–0.95

The relationship between the ACIC score and attributable risk of CHD for patients within each clinic is illustrated in Figure 1. Clinics were divided into groups according to size and quartile of ACIC score. Of particular interest is the finding that the mean attributable risk at the clinic level drops with improving ACIC scores for small clinics, but not for large clinics. This may explain why there was no relationship between clinic size and attributable risk in the models shown in Table 3. Overall, there was no significant difference between small and large clinics in either ACIC score or the mean attributable risk for each clinic (data not shown).

DISCUSSION

The 10-year CHD risk attributable to modifiable risk factors was associated with the degree to which care provided in each clinic was consistent with the CCM in these primary care clinics. This was not true for the absolute risk. As discussed above, ACIC scores are anchored to 4 categories regarding the degree to which care is consistent with the CCM; limited, basic, good, and fully developed. Given the range of scores across these categories, compared with a clinic with full implementation of the CCM, a clinic with

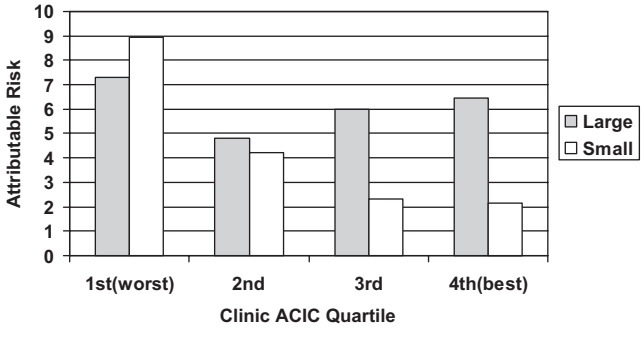

FIGURE 1. Attributable risk, clinic size, and ACIC score.

limited implementation would have an ACIC score that would be at least 4 points higher. This would translate into a decrease in risk attributable to modifiable risk factors by 66%, for example, from 5.0% to 1.7%. These findings contribute to the growing body of evidence documenting a relationship between how care is provided in primary care clinic settings and patient outcomes, although this study is the first to document a relationship between care consistent with the CCM and 10-year risk of a fatal or nonfatal CHD event among patients with type 2 diabetes.

Three other studies have found a relationship between the how care delivered conforms to the CCM and a few of the intermediate clinical outcomes that are incorporated into the UKPDS risk engine. A recent study by Nutting and colleagues demonstrated a relationship between how care is consistent with the CCM and control of A1c and lipids.[19] Their measure of the CCM was not the ACIC score reported here, rather a survey developed by the authors to measure physician perception of the use of CCM elements. Feifer and colleagues found a positive association between ACIC score and a composite score for quality of care that included control of risk factors for diabetes.[20] Finally, Solberg and colleagues reported that improvement in 2 subscales in the ACIC over 2.5 years, clinical information systems and decision support, was associated with improvement in a composite measure of the percentage of patients with A1c <7 and low-density lipoprotein cholesterol <100 across 17 clinics.[21] The study reported here adds to this body of evidence concerning organizational attributes of primary care clinics and an important patient outcome: the 10-year risk of a fatal or nonfatal CHD event such as myocardial infarction.

Why should the relationship between the consistency of care with the CCM and CHD risk be true for small clinics, but not for larger clinics? It is possible that redesigning the care delivery system around the CCM in small clinics has a more direct effect on the care provided to patients with type 2 diabetes than in larger clinics. It is also possible that although there are structural elements consistent with the CCM in larger clinics, such as diabetes educators, these services may not be readily available to all patients across all providers in the clinic, compared with smaller clinics. Finally, clinicians in larger clinics may incorrectly perceive that care delivered in their clinic is consistent with the CCM when, in fact, it is not.

Also of note is the finding that if all 4 modifiable risk factors were at guideline recommended levels, the absolute risk of fatal or nonfatal CHD would decrease from 16.2% to 11.2%. That is, if all modifiable risk factors were well controlled, one would observe a one-third decrease in the 10-year risk of fatal or nonfatal myocardial infarction. In 1 clinic the average absolute risk would drop from 12.4% to 6.2%, a 50% decline. These declines reflect the overall poor control of modifiable risk factors: only 15.4% were at guideline recommended levels for A1c, BP, and lipids. This amount of poor control is consistent with other recent studies documenting inadequate control of A1c, BP, and lipids among patients with type 2 diabetes.[22–24] For example, national population data reveal that only 7.3% of adults with previously diagnosed diabetes attained recommended goals for all three.[23]

Limitations of this study include its cross-sectional observational design, method of subject recruitment, a limited number of primary care clinics in one geographic region in the United States, and difficulty interpreting a total score for care consistent with the CCM. Regarding study design, there may be other unmeasured factors that are related to both CHD risk and clinic characteristics, limiting our ability to draw any conclusions about causality. In addition, by applying our strict inclusion criteria, the average number of patients per clinic decreased the reliability of the results from the random effects model. However, a particular strength of the study is use of a diversity of small, independent, mixed-payer clinics, which are reflective of the types of settings where most patients with type 2 diabetes receive their diabetes care. By recruiting consecutive patients presenting for care in each clinic, it is possible that subjects who enrolled had worse control of their diabetes or other chronic disease, had worse overall health status or a greater number and severity of comorbidities. It is encouraging to note that, as previously mentioned, control of A1c, BP, and lipids in this sample were little different that nationally representative samples.

Not only do the items on the ACIC instrument provides little detail and few examples regarding what does and does not qualify under each domain such as community resources or decision support, it is difficult to interpret the meaning of the total ACIC score as it is a composite score comprised of 6 different domains. We did find that the CCM component least likely to be fully implemented in these clinics was clinical information systems, a finding that is consistent with the literature on the lack of penetration of electronic health records and other computerized information management systems into primary care settings.[25] Unfortunately, our small sample size prohibited an analysis that would inform us concerning the relative importance of each domain for risk of fatal or nonfatal myocardial infarction. Further studies with larger numbers of clinics are needed.

CONCLUSIONS

This study adds to the growing body of evidence about the importance of how care delivery is organized in the primary care clinic and highlights the need for effective interventions to achieve sustainable change in these small, mixed-payer primary care settings.[26,27] These types of bedside to community translational research studies are needed if we are ever to close the gap and fully implement the evidence of controlled clinical trials concerning prevention of fatal or nonfatal CHD in patients with type 2 diabetes.[28]

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