Impact of a Community-Based Multiple Risk Factor Intervention on Cardiovascular Risk in Black Families With a History of Premature Coronary Disease

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Background—Black subjects with a family history of premature coronary heart disease (CHD) have a marked excess risk, yet barriers prevent effective risk reduction. We tested a community-based multiple risk factor intervention (community-based care [CBC]) and compared it with “enhanced” primary care (EPC) to reduce CHD risk in high-risk black families.

Methods and Results—Black 30- to 59-year-old siblings of a proband with CHD aged <60 years were randomized for care of BP ≥140/90 mm Hg, LDL cholesterol ≥3.37 mmol/L, or current smoking to EPC (n = 168) or CBC (n = 196) and monitored for 1 year. EPC and CBC were designed to eliminate barriers to care. The CBC group received care by a nurse practitioner and a community health worker in a community setting. The CBC group was 2 times more likely to achieve goal levels of LDL cholesterol and blood pressure compared with the EPC group (95% CI, 1.11 to 4.20 and 1.39 to 3.88, respectively) with adjustment for baseline levels of age, sex, education, and baseline use of medications. The CBC group demonstrated a significant reduction in global CHD risk, whereas no reduction was seen in the EPC group (P < 0.0001).

Conclusions—Eliminating known barriers may not be sufficient to reduce CHD risk in primary care settings. An alternative community care model that addresses barriers may be a more effective way to ameliorate CHD risk in high-risk black families. (Circulation. 2005;111:1298-1304.)

Key Words: risk factors ■ cholesterol ■ hypertension ■ trials ■ prevention

Coronary heart disease (CHD) aggregates in families, particularly at young ages. The risk is highest in siblings of probands, with relative risks from 2 to 12 times that of the general population. Most familial CHD studies have been in whites. To date, the importance of a family history of CHD in blacks has received little attention, though blacks with a family history have a relative risk that is as high as 5 times that of the general population. In the Heritage Family Heart Study, familial aggregation of CHD risk was stronger in blacks than in whites. Among first-degree relatives of CHD probands, sibs bear the greatest increased risk, likely as a result of genes and shared environment. The prevalences of smoking; untreated, undertreated, and poorly controlled hypertension; and hypercholesterolemia are particularly high in blacks with a family history of premature CHD.

Traditional medical models of CHD risk reduction have not been effective in black populations. Access to care, cultural competence of providers, trust in the healthcare system, work and child-care needs, opportunities for a healthy diet and exercise, educational resources, and access to affordable pharmacotherapy have all been cited as causally related to health disparities among blacks. Few studies have examined care models that explicitly eliminate known barriers to effective multiple CHD risk factor reduction in high-risk black populations, such as families with premature CHD. It has been suggested that if these barriers were addressed in traditional primary care, there would be a notable reduction in risk factors, sufficient to at least partially ameliorate racial disparities in CHD risk. On the other hand, an important major barrier may be discordance of the primary care delivery model itself with the culture of the black community. The present study was designed to determine the relative effectiveness of an alternative model of community-based care (CBC) provided in the black community compared with “enhanced” primary care (EPC), in which the major barriers are addressed in both groups: the former in
a way that is designed by community members and the latter by enhancing the traditional method of primary care delivery. The outcomes include both individual risk factors and predicted global 10-year risk of any CHD event or of a “hard” CHD event (myocardial infarction or sudden cardiac death).

Methods

The study was approved by the institutional review board at the Johns Hopkins Medical Institutions and the institutional review boards at participating hospitals (see Acknowledgments).

Subjects and Design

Siblings were recruited from black probands aged <60 years who were identified at the time of hospitalization for a CHD event in any of 10 Baltimore hospitals. Sibs were eligible if they were aged between 30 and 59 years with no known history of CAD, no chronic glucocorticosteroid therapy, no autoimmune disease, no current cancer therapy, and no immediate life-threatening comorbidity. Among probands with eligible sibs, <2% declined to provide access to their brothers and sisters. Potentially eligible sibs were sent a letter describing the study with a refusal postcard option to return, which occurred in 3%. Sibs were called to verify their medical history and to enroll them. The absence of CHD was verified with the primary care provider. Sibs with criterion risk factors were randomly assigned by family to a CBC intervention or EPC. All sibs in both groups were reexamined 1 year after treatment initiation.

Screening, Measurements, and Recommendations

After providing written informed consent, all sibs had a physical examination and medical history taken by a cardiologist. Blood pressure was measured according to the American Heart Association guidelines at 4 times over the day, and the average was used.

Height and weight were measured. Body mass index (BMI) was calculated from weight (kg) divided by the square of height (m²). After subjects had fasted for 12 hours overnight, blood was obtained for measurement of serum total cholesterol (TC), HDL cholesterol (HDL-C), triglyceride (TG), and glucose levels in the Johns Hopkins Chemistry Laboratory. LDL cholesterol (LDL-C) levels were estimated with the use of the Friedewald equation. Framingham sex-specific risk scoring equations were used to predict the risk of developing total CHD events over the next 10 years. Risk was calculated for each individual with the use of the average blood pressure, TC, HDL-C, age, and current smoking status. For prediction of 10-year total CHD risk, diabetes was entered as a dichotomous variable, present or absent. In siblings without diabetes, we also examined the prediction of hard CHD events from the unpublished Framingham equations used in the Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). We examined shifts in global 10-year risk of a hard event on the basis of modified ATP III risk strata.

Interviewer-administered questionnaires were used to elicit data on sex, race, education in years, comorbidity, diet, and exercise. Diet was assessed by means of the Block Food Frequency Questionnaire. Physical activity levels were assessed with the Stanford 7-Day Recall. Current cigarette smoking was assessed by self-report and was biochemically validated. Individuals were characterized as current smokers if they had smoked any cigarettes within the past week or if they had an expired carbon monoxide level >8 ppm on 2 successive readings.

Recommendations based on national guidelines and specific to the individual’s risk factor status were generated for all siblings and providers in both groups from a computerized program. Risk factor–triggered educational text messages were based on the Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II); the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI); and on smoking cessation guidelines issued by the Agency for Healthcare Research Quality (AHRQ). Dietary recommendations were based on the ATP II Step II diet. We also emphasized eliminating simple sugars (sweets) because we have previously found that sweets constitute a large portion of the excess calories in this population. A simple increase in daily walking and stair climbing was recommended with additional moderate exercise activities for at least 30 minutes per day, 4 days per week.

For LDL-C, the goal of therapy was =<3.37 mmol/L (130 mg/dL), and that for blood pressure was =<140/90 mm Hg. Pharmacotherapy recommendations were based on the national guidelines. For smokers, the goal was total abstinence, and we recommended nicotine replacement and/or bupropion as an adjunct to standard behavioral methods.

Randomization

Sibs with criterion risk factors were randomized to CBC or EPC with the use of a computer-generated randomization schema. Criterion risk factors included current smoking, a fasting LDL-C ≥3.37 mmol/L (130 mg/dL), and/or an average systolic blood pressure of ≥140 mm Hg or diastolic blood pressure of ≥90 mm Hg. All sibs in the same family were randomized together. Siblings with no criterion risk factors were given recommendations on healthy lifestyle and did not enter the trial.

CBC Intervention

Sibs randomized to CBC received care in 1 nonclinical site in the community that was designed by a community advisory panel. The site was easily accessible by bus lines and subway and was within walking distance for many sibs. The suite consisted of a comfortable conference room for counseling; a clinical room for phlebotomy and physical examination; an exercise room containing a treadmill, weights, Thera-Band resistive exercise equipment, and a choice of music; and a living room with a children’s play area. The original purpose of the exercise room was to evaluate shifts in exercise blood pressure with therapy and to expose people to the physical “experience” of exercise in a safe environment. Appointments were not necessary, and the Family Heart Center was open from 9 AM until 5 PM Monday through Friday, with evenings and Saturday appointments available if requested.

On each CBC visit, the nurse practitioner performed a brief physical assessment including blood pressure measurements. The nurse practitioner evaluated patients for pharmacotherapy and monitored compliance. The community health worker saw sibs for all dietary counseling, smoking cessation, and exercise counseling. The average total visit was 30 minutes. Telephone interventions to monitor progress were available. The progress of each sib was reviewed by the study physician with the CBC team twice monthly.

The nurse practitioner communicated all changes in pharmacotherapy with the primary care physician by mail. Health concerns that did not involve risk factors were referred to the primary care physician, and nurse practitioner involvement was proscribed. Primary care providers were asked to refrain from providing care for criterion risk factors and not to change related therapy. The decisions of how to apply the guidelines were within the full purview of the nurse practitioner. This was done to create a decision environment most like that of usual primary care providers.

All sibs requiring pharmacotherapy were given a pharmacy charge service (PCS) card that allowed them to obtain their risk factor prescriptions free of charge at any pharmacy. When a prescription was filled, a bill was generated that was paid from unrestricted funds provided to the study by several pharmaceutical companies (see Acknowledgments). The PCS service provided the study with information about whether prescriptions were filled.

Sibs also could attend 2 free evening sessions per week at the YMCA conducted by the community health worker. Sessions included aerobics, stretch exercises, Thera-Band resistance training, and water aerobics. The community health worker completed a YMCA standard training program for volunteers and also had basic life support training.
**EPC Intervention**

Sibs randomized to the EPC group received the same risk-specific materials. The primary care provider also received the results and recommendations and a copy of ATP II, JNC VI, and AHRQ smoking cessation guidelines as indicated. The PCS card was mailed to providers to give to their patients for free risk factor pharmacotherapy, and the benefit of the card was emphasized to the physician and the patient. Sibs were given a full explanation of the card and were instructed to ask their provider for it. EPC group sibs and their providers were also sent materials about access to the free YMCA programs. Sibs were informed about resources available from their provider, and providers were encouraged to use them for their patients. All written information was presented at an eighth grade level.

**Primary Outcome Measurements**

The major outcomes included changes in LDL-C level, in systolic and diastolic blood pressure, and in the 10-year Framingham Risk Score (FRS) for CHD events. For clinical utility, we also examined the percentage of sibs with each criterion risk factor achieving goal levels at 1 year.

We also determined shifts in the percentage of sibs in both groups for the very-low (<6%), low- (6% to 9%), intermediate- (10% to 20%), and high-risk (>20%) groups on the basis of the predicted 10-year risk of a hard CHD event in nondiabetic siblings.

**Statistical Methods**

Intention-to-treat analyses were used for all outcomes. Continuous variables were examined for normality with the Kolmogorov-Smirnov D statistic. Baseline characteristics of the groups were compared with unpaired t tests. The between-group changes from baseline to follow-up were evaluated in bivariate analyses with the use of ANCOVA models of the postintervention levels of continuous variables adjusted for baseline levels, and contingency table arrays were evaluated with the \( \chi^2 \) statistic for categorical variables. Three separate multiple regression models were used for 3 primary outcomes to determine the impact of the intervention group after adjustment for other influential variables. To account for examination of 3 to 4 outcomes, on the basis of the Bonferroni correction method, we required a significance level of \(<0.0125\). We examined the impact of the interventions using the posttest values adjusted for the baseline values of all continuous risk factors to minimize biases often associated with change scores.\(^{25}\) Multiple logistic regression analyses were also used to examine attainment of risk factor goal levels adjusted for salient variables and for baseline levels of risk factors. The number of smokers who quit was too small to perform stable multivariable analyses predicting cessation. All regression models were adjusted for nonindependence of families with the use of the generalized estimating equations (GEE).\(^{26}\)

**Results**

**Characteristics**

The probands had a mean age of 49±7 years; 56% were women and were identified at the time of hospitalization for a documented CHD event, primarily revascularization (68%).

Randomization resulted in the assignment of 168 siblings representing 92 families to the EPC group and 196 siblings representing 102 families to the CBC group; 104 sibs had no criterion risk factors. There were 43 participating families with 1 or more siblings who did not have a criterion risk factor, and these families were distributed similarly by intervention group. The groups were similar on the distributions of sociodemographic variables, although the EPC group was slightly better educated (Table 1). Sibs were, on average, middle-aged with a high school education. Family size distributions were similar in both groups. Although 80% had

| TABLE 1. Baseline Sociodemographic and Comorbidity Characteristics by Intervention Group |
|---------------------------------|-----------------|-----------------|---|
| **Characteristic**              | **CBC Group**   | **EPC Group**   | **P**  |
| Age, mean±1 SD, y               | 47.6±7          | 47.9±6          | 0.64  |
| Education, mean±1 SD, y         | 12.5±2          | 13.1±2          | 0.02  |
| Percent female                  | 61              | 66              | 0.34  |
| Percent with healthcare insurance| 80              | 80              | 0.98  |
| Percent employed                | 80              | 77              | 0.57  |
| Percent married                 | 39              | 45              | 0.27  |
| Percent with regular primary care provider | 73 | 74 | 0.75 |
| Percent diabetic                | 18              | 12              | 0.11  |

employer or private health insurance, fewer had a regular primary care provider. The majority were women, and there was a high prevalence of diabetes. At baseline, the groups had similar levels of risk factors, diet, exercise, and 10-year predicted risk of total and hard CHD events (Table 2).

**Exposure to Interventions by Group**

In both groups, 94% saw their primary care provider after screening. The average illness-related visits to their primary care provider was 4.4 in the CBC group and 4.5 in the EPC group. CBC participants had an average of 7.4±8 CBC encounters in the year of treatment. The average encounter time was 30 minutes. A third of all CBC encounters were by telephone; 81% of CBC participants had at least 1 in-person encounter. The Saturday option was never exercised, and the evening options were rarely used (5 sibs).

The PCS card was given to 48% of the CBC group compared with 21% in the EPC group (\( P<0.0001 \)); of those who received the cards, 74% of the CBC group used it to fill prescriptions, compared with 34% of the EPC group (\( P<0.0001 \)). In the CBC group, 20% participated in regular YMCA exercise, whereas none of the EPC group used the free YMCA exercise (\( P<0.0001 \)).

**Comparisons of Interventions**

We found that 73% of the CBC group and 74% of the EPC group returned for follow-up. Acceptance of the assigned intervention groups occurred in 100% of all participants, and all received recommendations.

**Changes in Risk Factor Outcomes**

There were significant improvements in the primary outcomes within both groups, with the CBC group usually showing more favorable changes. Figure 1 demonstrates the unadjusted differences between baseline and 1-year follow-up in the percentage achieving goal levels. Table 2 shows that between-group differences in the primary outcome levels of LDL-C and blood pressure adjusted for baseline levels were statistically significant. Favorable changes were greater in the CBC group. LDL-C, smoking, and shifts in the FRS showed the greatest differences between groups, with the greatest improvement in the CBC group. Systolic and diastolic blood pressures were significantly different by group, with the more notable improvements in the CBC.
group. The FRS for total CHD showed a greater decrement in the CBC group (25.5%) than in the EPC group (3.3%) (P<0.0001); there were also between-group differences in levels of hard CHD risk in the nondiabetic siblings, with a 27.4% reduction in risk in the CBC group and a 2.3% decrease in the EPC group, which was also highly significantly different by group. Lipid-lowering and antihypertensive therapy increased significantly in both groups but more so in the CBC group (Table 2). Of the lipid-lowering agents, 97% were statins. There were no differences between groups so in the CBC group (Table 2). Of the lipid-lowering agents, 97% were statins. There were no differences between groups.

**TABLE 2. Risk Factors, Global Risk, Diet, Exercise, and Medications by Group at Baseline and Follow-Up**

<table>
<thead>
<tr>
<th></th>
<th>CBC Group (n=196)</th>
<th>EPC Group (n=168)</th>
<th>P†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline 1 Year</td>
<td>Baseline 1 Year</td>
<td></td>
</tr>
<tr>
<td>LDL-C, mmol/L</td>
<td>3.59±1.0 3.06±1.0</td>
<td>3.51±1.0 3.38±1.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>TG, mmol/L</td>
<td>1.47±1.1 1.35±1.0</td>
<td>1.37±0.72 1.34±0.7</td>
<td>0.2769</td>
</tr>
<tr>
<td>HDL-C, mmol/L</td>
<td>1.40±0.42 1.40±0.41</td>
<td>1.39±0.45 1.39±0.43</td>
<td>0.9770</td>
</tr>
<tr>
<td>SBP, mm Hg</td>
<td>139±16 130±14</td>
<td>137±16 134±17</td>
<td>0.0001</td>
</tr>
<tr>
<td>DBP, mm Hg</td>
<td>89±10 84±9</td>
<td>86±11 85±10</td>
<td>0.0002</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>31.9±6.3 31.8±6.4</td>
<td>31.1±6.7 31.1±6.7</td>
<td>0.8132</td>
</tr>
<tr>
<td>Glucose, mmol/L</td>
<td>6.10±2.9 5.97±2.7</td>
<td>5.77±2.5 6.07±3.0</td>
<td>0.0274</td>
</tr>
<tr>
<td>FRS (total events)</td>
<td>9.45±6.9 7.04±4.9</td>
<td>9.02±6.8 8.72±6.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>FRS (hard events)‡</td>
<td>4.63±4.7 3.36±4.0</td>
<td>4.59±5.3 4.38±5.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Percent energy from total fat</td>
<td>39.2±6.8 38.6±6.7</td>
<td>37.8±6.1 38.6±6.3</td>
<td>0.1210</td>
</tr>
<tr>
<td>Percent energy from sweets</td>
<td>17.7±11 15.8±9.3</td>
<td>19.9±9.8 18.6±10</td>
<td>0.0685</td>
</tr>
<tr>
<td>Energy expenditure, mJ/d</td>
<td>10.4±3.0 10.8±3.0</td>
<td>10.8±3.4 10.4±2.8</td>
<td>0.0203</td>
</tr>
<tr>
<td>Percent current smokers</td>
<td>37 31 43 40</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Percent taking antihypertensive agents</td>
<td>35 52 32 41</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Percent taking lipid-lowering agents</td>
<td>4 36 8 15</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
</tbody>
</table>

Values are mean±1 SD. SBP indicates systolic blood pressure; DBP, diastolic blood pressure.

†Between-groups ANCOVA, using the postintervention values adjusted for baseline.

‡Framingham hard risk was calculated for n=309, excluding all diabetics.

Multiple linear regression analyses predicting the baseline-adjusted postintervention levels of LDL-C, systolic blood pressure, and FRS for total CHD events are shown in 3 separate multivariable models in Table 3. The CBC intervention remained a strong predictor of blood pressure and FRS outcomes after multivariable adjustment for other influential variables, but the 0.0125 level of significance was not reached for LDL-C on the basis of Bonferroni corrections. The use of lipid-lowering therapy was the strongest predictor of reduction in LDL-C. Male sex was a significant predictor of LDL-C outcome after multivariate adjustment. For the FRS, the use of blood pressure medications was highly significant. A total of 64% of the variance in 1-year LDL-C was explained by the model after adjustment for baseline levels, whereas the variance explained was less but still notable for systolic blood pressure. Only a small amount of the variance in the FRS for total CHD events was explained by the model.

Table 4 demonstrates that the CBC group was twice as likely to achieve goal levels of LDL-C and blood pressure compared with the EPC group, after adjustment for all other variables and baseline values of LDL-C. Achievement of the LDL-C goal was 13 times greater in people receiving a lipid-lowering medicine compared with those who did not. Men achieved a benefit that was >2 times that of women. Only the CBC intervention group was a significant predictor of achieving the blood pressure goal level after adjustment for other influential variables.

**Changes in Lifestyle Factors**

Dietary fat and sweets were not significantly different by group (Table 2). There was a marginally significant between-group difference in energy expended, with an increment in |
the CBC group and a decrease in the EPC group. BMI did not change significantly in either group. There was a 16.2% decrease in smoking among smokers in the CBC group and a 7.0% reduction in smoking in the EPC group, which was highly significant when adjusted for baseline smoking prevalence.

Changes in the Distribution of Framingham Risk for Hard Coronary Disease Events

Figure 2 shows the between-group significant shifts in the 10-year prediction of hard events ($P<0.0001$). In the CBC group, an increase in the number of individuals in the very-low-risk group, a significant reduction in the intermediate-risk group, and a small reduction in the high-risk group were observed. Modest shifts occurred in the EPC group.

Discussion

There is little question that high-risk blacks fail to receive appropriate care for CHD risk reduction, despite a greater prevalence of risk factors and higher case fatality rates. Recent expert reviews of health disparities have concluded that effective strategies remain elusive and that studies are needed. This is the first trial, to our knowledge, that was designed explicitly to test the comparative effectiveness of a community intervention model and a primary care model in which the major barriers are addressed in both groups. The results offer several insights that address disparities. First, sibs assigned to the CBC intervention were more likely to reduce their levels of LDL-C and blood pressure and also showed a significant reduction in global CHD risk. Second, the EPC group demonstrated a smaller improvement in risk factors, suggesting that barrier-reducing enhancements to primary care may improve individual risk factor outcomes only modestly. Third, even in the best-case scenario in which the major well-known barriers to care have been markedly reduced, risk factor goals were not attained by a relatively large number of individuals in both groups. Fourth, even though individual risk factors changed in the EPC group, the magnitude of change was not sufficient to shift global CHD risk for either total or hard CHD events.

The superior results in the CBC group may have been mediated in part through the community health worker, who served as a culturally sensitive navigator through the systems needed to alter risk factors, ie, how to fill and use a prescription, how to shop for and prepare healthier foods, and how to access an exercise facility. The nurse practitioner was needed to alter risk factors, ie, how to fill and use a prescription, how to shop for and prepare healthier foods, and how to access an exercise facility. The nurse practitioner was needed to alter risk factors, ie, how to fill and use a prescription, how to shop for and prepare healthier foods, and how to access an exercise facility. The nurse practitioner was needed to alter risk factors, ie, how to fill and use a prescription, how to shop for and prepare healthier foods, and how to access an exercise facility.
Efforts to garner trust were a negotiated process between sibs and the nurse practitioner or community health worker. Without negotiation, when people encounter side effects, concerns about costs, mistrust, or fear of the drug, they may be more likely to elect volitional noncompliance.30,31 It has been suggested that interventions that address these same barriers in primary care settings could eliminate disparities in US health care.13,32 In our study, however, the impact of interventions to address most known barriers did not shift global CHD risk in primary care settings. CBC, with an alternative infrastructure, in contrast, showed a significant shift in predicted CHD risk. Because the EPC settings had patient education materials, free medications, exercise opportunities, and a comprehensive screening with results and expert recommendations, failure to shift global CHD risk suggests that even with the putative major barriers addressed, the usual care system infrastructure may not be optimal for risk reduction in current black culture.13

Limitations of the Study
A cost-effectiveness analysis was not conducted, and the long-term benefits are not known. We are not able to determine specifically which elements of the interventions were the most efficacious. The community-designed intervention resulted in a coordinated novel care system that worked well in a real-world setting. Still, it remains possible that if the CBC elements were applied differently or in a population with lower educational levels, the impact may not be the same.

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Disclosure
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References

Figure 2. Shifts in predicted 10-year risk for hard events based on the Framingham risk equation at baseline and follow-up in CBC (A) and EPC (B) groups in nondiabetic siblings (n=308). Diabetics were not included in these analyses. High risk is >20%; intermediate risk, 10% to 20%; low risk, 6% to 9%; and very low risk, <6%.


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