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## Effectiveness of Therapeutic Lifestyle Changes in Patients With Hypertension, Hyperlipidemia, and/or Hyperglycemia

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**In this prospective study of 2,390 ethnically diverse men and women, we evaluated the clinical effectiveness of 12 weeks of participation in a community-based lifestyle management program in helping patients who had hypertension, hyperlipidemia, and/or impaired fasting glucose or diabetes mellitus achieve goal risk factor levels without using pharmacotherapeutic agents. Although further research is warranted, the findings clearly show that many patients who have conventional risk factors for coronary heart disease can achieve goal levels without medications within 12 weeks of initiating therapeutic lifestyle changes and refute the notion that intensive lifestyle intervention is not worth the effort. ©2004 by Excerpta Medica Inc.**

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**R**ecent studies have emphasized the need to intensify efforts aimed at the control of conventional risk factors for coronary heart disease.<sup>1,2</sup> National clinical guidelines have promulgated therapeutic lifestyle changes as a standard of care in the management of conventional risk factors.<sup>3,4</sup> However, because of the widespread availability of powerful medications, the value of therapeutic lifestyle changes per se in contemporary medical practice is often discounted by clinicians, health insurers, and patients. In this prospective study of 2,390 patients, we evaluated the clinical effectiveness of 12 weeks of therapeutic life-

style changes in helping patients who had hypertension, hyperlipidemia, and/or impaired fasting glucose or diabetes mellitus achieve goal risk factor levels without using pharmacotherapeutic agents.

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A cohort of 2,390 consecutive adult patients who completed initial and 12-week follow-up assessments as part of their participation in a comprehensive, community-based lifestyle management program comprised the study population. Patients were self-referred or referred by a physician to participate in the program and met  $\geq 1$  of the following criteria: baseline (i.e., at program entry) systolic blood pressure (BP)  $\geq 140$  mm Hg and/or diastolic BP  $\geq 90$  mm Hg and not taking antihypertensive medications at baseline or follow-up, baseline fasting level  $\geq 100$  mg/dl for low-density lipoprotein cholesterol and not taking antilipemic medications at baseline or follow-up, or baseline fasting glucose level  $\geq 110$  mg/dl and not taking antidiabetic medications at baseline or follow-up. Written informed consent was obtained from each patient. Baseline clinical characteristics are listed in Table 1.

The lifestyle management program was administered by non-physician health care providers who were guided by a computerized participant management system, as previously described.<sup>5,6</sup> Briefly, the program included the following core components: (1) initial assessment, including completion of a comprehensive medical history questionnaire and measurement of height, weight, waist circumference, seated BP, fasting serum lipids and lipoproteins, and fasting glucose; (2) computer generation of risk factor goals based on national clinical guidelines<sup>3,7–11</sup> and an action plan for achieving these goals through comprehensive lifestyle changes; (3) action plan implementation, including 1-on-1 behaviorally oriented counseling (face to face or, if the patient preferred, by telephone and the Internet) to help each patient acquire the skills, motivation, and support needed to implement and adhere to an individually prescribed

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**TABLE 1** Baseline Demographic and Clinical Characteristics of Subjects (n = 2,390)

Variable	Values
Age (yrs)	50 ± 11
Men	33%
Women	67%
African-American	23%
Caucasian	70%
College education*	78%
Known atherosclerotic cardiovascular disease	9%
Previous myocardial infarction	2%
Previous coronary artery bypass graft surgery	2%
Previous percutaneous transcatheter revascularization	3%
Previous stroke	1%
Known diabetes	11%
Framingham 10-year CHD risk score†	8.1 ± 6.4%
Current cigarette smoker	8%
Sedentary lifestyle‡	58%
Not attempting to eat a low-fat/cholesterol diet	85%
Systolic BP (mm Hg)	128 ± 17
Diastolic BP (mm Hg)	80 ± 10
Total cholesterol (mg/dl)	213 ± 38
Low-density lipoprotein cholesterol (mg/dl)	134 ± 31
High-density lipoprotein cholesterol (mg/dl)	52 ± 15
Triglycerides (mg/dl)	145 ± 116
Fasting glucose (mg/dl)	103 ± 31
Body mass index (kg/m <sup>2</sup> )	31.6 ± 7.3
Weight (lb)	196 ± 48
Waist circumference (inches)	37.7 ± 6.6

Data are presented as means ± SD or percentages.  
 \*At least 1 year of college education.  
 †Ten-year risk for CHD calculated with Framingham regression equations in subjects who had no known atherosclerotic cardiovascular disease.  
 ‡Currently not performing ≥20 minutes of moderate or higher intensity aerobic exercise for ≥3 days/week.  
 CHD = coronary heart disease.

**TABLE 2** Effect of 12 Weeks of Therapeutic Lifestyle Changes on Control of Systolic Blood Pressure in Subjects Not Taking Antihypertensive Medications, Diastolic Blood Pressure in Subjects Not Taking Antihypertensive Medications, LDL-Cholesterol in Subjects Not Taking Antilipemic Medications, and Fasting Glucose in Subjects Not Taking Antidiabetic Medications: Subjects With Abnormal Baseline Values†

Outcomes Measurement	Baseline	Follow-up	Change
Systolic BP (mm Hg) (n = 237)	149 ± 11	133 ± 13	-17 ± 14*
Systolic BP (% at goal‡)	0	64	64*
Diastolic BP (mm Hg) (n = 199)	94 ± 5	84 ± 8	-10 ± 9*
Diastolic BP (% at goal‡)	0	67	67*
LDL cholesterol (mg/dl) (n = 957)	144 ± 28	135 ± 30	-9 ± 25*
LDL cholesterol (% at goal‡)	53	64	11*
Fasting glucose (mg/dl) (n = 268)	144 ± 43	127 ± 39	-17 ± 44*
Fasting glucose (% at goal‡)	0	39	39*

Where appropriate, values are mean ± SD. Changes from baseline were statistically significant where indicated (\*p ≤ 0.05).  
 †Systolic BP ≥140 mm Hg; diastolic BP ≥90 mm Hg; LDL cholesterol ≥100 mg/dl; fasting glucose ≥110 mg/dl.  
 ‡Systolic BP <130 mm Hg for subjects who had diabetes and/or chronic renal disease, <140 mm Hg for other subjects; diastolic BP <80 mm Hg for subjects who had diabetes and/or chronic renal disease, <90 mm Hg for other subjects; LDL cholesterol at goal using national criteria<sup>3</sup> (namely <100 mg/dl for subjects who have coronary heart disease or coronary heart disease risk equivalents; <130 mg/dl for other subjects who had ≥2 major coronary heart disease risk factors; and <160 mg/dl for other subjects who had 0 to 1 major coronary heart disease risk factors); fasting glucose <110 mg/dl.  
 LDL = low-density lipoprotein.

home-based exercise plan,<sup>12</sup> meal plan,<sup>13</sup> and other appropriate lifestyle changes; and (4) reassessment after ~12 weeks (not all biometric and laboratory measurements were performed in all patients).

To evaluate the effect of the lifestyle management program (as opposed to the combined effect of lifestyle management and drug therapy), 2 sets of data analyses were performed. First, changes from baseline were analyzed for multiple risk factors in those patients (n = 1,402) from the study cohort who were not taking antihypertensive, antilipemic, or antidiabetic medications at baseline or follow-up. Second, additional analyses were performed on the following 4 groups of patients from the study cohort: patients who had a baseline systolic BP ≥140 mm Hg, had systolic BP measured at follow-up, and were not taking antihypertensive medications at baseline or follow-up (n = 237, group 1); patients who had a baseline diastolic BP ≥90 mm Hg, had diastolic BP measured at follow-up, and were not taking antihypertensive medications at baseline or follow-up (n = 199, group 2); patients who had a baseline low-density lipoprotein cholesterol level ≥100 mg/dl, had low-density lipoprotein cholesterol measured at follow-up, and were not taking antilipemic medications at baseline or follow-up (n = 957, group 3); and patients who had a baseline fasting glucose level ≥110 mg/dl, had fasting glucose mea-

sured at follow-up, and were not taking antidiabetic medications at baseline or follow-up (n = 268, group 4). For each group, percentages of patients who had risk factor values at goal were calculated at baseline and follow-up using the risk factor goals listed in Table 2.

For categorical variables, statistical significance of differences between baseline and follow-up values was analyzed with chi-square tests. For continuous variables, statistical significance of changes from baseline was analyzed with 2-sided paired *t* tests. Statistical significance was established at the 0.05 confidence level. When appropriate, values are expressed as mean ± SD.

Patients completed approximately 64% of the scheduled counseling sessions (9 ± 6 of 14 scheduled sessions per patient). Changes in multiple risk factors in patients who did not take antihypertensive, antilipemic, or antidiabetic medications are listed in Table 3. In addition to the improvements listed in Table 3, 29 of the 119 patients (25%) who were current cigarette smokers at baseline reported that they had quit smoking cigarettes at follow-up (p ≤ 0.05). Framingham 10-year risk scores for coronary heart disease were determined at baseline and follow-up in 700 patients who had no known atherosclerotic cardiovascular disease and decreased from 6.8 ± 5.7% to 5.9 ±

**TABLE 3** Effect of 12 Weeks of Therapeutic Lifestyle Changes on Coronary Heart Disease Risk Factors: Subjects Not Taking Antihypertensive, Antilipemic, or Antidiabetic Medications at Baseline or Follow-up

Outcome Measurement	All Subjects	Subjects With Abnormal Baseline Values <sup>†</sup>
Systolic BP (mm Hg)	-5 ± 13* (n = 1,386)	-17 ± 14* (n = 205)
Diastolic BP (mm Hg)	-3 ± 9* (n = 1,386)	-10 ± 9* (n = 181)
Total cholesterol (mg/dl)	-11 ± 28* (n = 711)	-25 ± 31* (n = 219)
LDL cholesterol (mg/dl)	-8 ± 26* (n = 701)	-9 ± 26* (n = 678)
HDL cholesterol (mg/dl)	-1 ± 9 (n = 710)	3 ± 7* (n = 149)
Triglycerides (mg/dl)	-11 ± 65* (n = 709)	-42 ± 84* (n = 278)
Fasting glucose (mg/dl)	-2 ± 20 (n = 571)	-18 ± 42* (n = 96)
Body mass index (kg/m <sup>2</sup> )	-0.6 ± 1.2* (n = 1,402)	-0.8 ± 1.2* (n = 1,111)
Weight (lb)	-4 ± 7* (n = 1,402)	-5 ± 8* (n = 1,111)
Waist circumference (inches)	-0.5 ± 2.4* (n = 1,249)	
Men		-1.6 ± 3.0* (n = 129)
Women		-1.1 ± 2.4* (n = 379)

Values are mean ± SD. Changes from baseline were statistically significant where indicated (\*p ≤ 0.05).  
<sup>†</sup>Systolic BP ≥ 140 mm Hg; diastolic BP ≥ 90 mm Hg; total cholesterol ≥ 240 mg/dl; LDL cholesterol ≥ 100 mg/dl; HDL cholesterol < 40 mg/dl; triglycerides ≥ 150 mg/dl; fasting glucose ≥ 110 mg/dl; body mass index ≥ 25 kg/m<sup>2</sup>; weight, body mass index ≥ 25 kg/m<sup>2</sup>; waist circumference, men > 40 inches, women > 35 inches.  
HDL = high-density lipoprotein. Other abbreviation as in Table 2.

4.8%, representing a 13.2% decrease in risk (p ≤ 0.05). Of these patients, those who had a baseline score ≥ 10% (n = 174) decreased their risk by 18.5% (14.6 ± 5.5% to 11.9 ± 5.2%, p ≤ 0.05) and those who had a baseline score ≥ 20% (n = 39) decreased their risk by 23.4% (23.1 ± 4.9 to 17.7 ± 6.4%, p ≤ 0.05).

The percentage of patients in groups 1 to 4 who had risk factor values at goal levels at baseline and at follow-up is presented in Table 2. In addition to the improvements presented in Table 2, 37% of patients (n = 56) in group 4 who had a baseline fasting glucose compatible with a diagnosis of diabetes mellitus (i.e., ≥ 126 mg/dl, n = 151) decreased that value to < 126 mg/dl.

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National clinical guidelines for the management of hypertension, hyperlipidemia, and impaired fasting glucose/diabetes mellitus have advocated a multifactorial lifestyle approach to decreasing the risk for coronary heart disease. This approach has been designated “therapeutic lifestyle changes” and includes exercise training, correct nutrition, and other appropriate lifestyle interventions.<sup>3</sup> There is abundant scientific evidence on the efficacy of each of the individual components of therapeutic lifestyle changes in the management of conventional risk factors.<sup>3,13,14</sup> There is also a growing body of published data on the efficacy of the simultaneous implementation of the multiple interventions that comprise therapeutic lifestyle changes.<sup>15–18</sup> The present study adds to the existing publications by reporting on the effectiveness (i.e., extent to which therapeutic lifestyle changes do work in actual practice) rather than on the efficacy (i.e., determining whether therapeutic lifestyle changes can work when administered in a clinical trial) of therapeutic lifestyle changes in the control of conventional risk factors.

The major strength of the present study is the

involvement of a relatively large number of ethnically diverse men and women who participated in an existing operational community-based lifestyle management program rather than in a clinical trial, the conditions of which may be difficult to replicate in the “real world.” Potential limitations include the absence of a control group with no intervention, regression to the mean in patients who had abnormal baseline risk factor values, and the relatively short duration of follow-up. In addition, the present findings cannot necessarily be extrapolated to patients who have more marked increases in risk factors than those of subjects in this study.

Although further research is warranted, these data clearly show that many patients who have conventional risk factors can achieve goal levels without medications within 12 weeks

of initiating therapeutic lifestyle changes and refute the notion that intensive lifestyle intervention is not worth the effort. The present findings have important implications for physicians and their patients in translating national clinical guidelines on risk factor management into medical practice and personal behavior change. Moreover, therapeutic lifestyle changes can generally be implemented less expensively than most medications and, unlike single-drug therapy, favorably affect multiple risk factors. Therefore, these findings also have potentially important policy implications for health care payers, including the federal government, which often does not provide reimbursement for therapeutic lifestyle changes but currently provides or intends to provide prescription drug coverage.

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## Comparison of Levels of Large and Small High-Density Lipoprotein Cholesterol in Asian Indian Men Compared With Caucasian Men in the Framingham Offspring Study

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Asian Indians have a higher incidence of coronary artery disease (CAD) than do other ethnic groups, despite similar standard risk factors and lipid profiles. The large subclass of high-density lipoprotein (HDL) cholesterol is predominantly associated with protection against coronary artery disease. We compared various lipoprotein concentrations and sizes in 211 healthy Asian Indian men with those in 1,684 Caucasian men from the Framingham Offspring Study as measured by nuclear magnetic resonance spectroscopy. Concentrations of HDL cholesterol were similar in the 2 groups, but concentrations of large HDL cholesterol were lower and concentrations of small HDL cholesterol were significantly higher in Asian Indian than in Caucasian men. HDL particle size was smaller in Asian Indians. Levels of low-density lipoprotein cholesterol, low-density lipoprotein particle

size, and prevalence of pattern B were similar in the 2 groups. ©2004 by Excerpta Medica Inc. (Am J Cardiol 2004;94:1561–1563)

Extensive prospective epidemiologic studies have consistently demonstrated that levels of high-density lipoprotein (HDL) cholesterol are inversely related to coronary artery disease (CAD). This relation is strong, graded, and independent of other lipid and nonlipid risk factors.<sup>1,2</sup> HDL cholesterol particles are predominantly involved in reverse cholesterol transport and mediate the removal of cellular cholesterol from cells. The prevailing view is that this cardioprotective effect may be largely restricted to the larger HDL subclass particles, whereas small HDL particles are associated with decreased cardiac protection or even an increased risk of CAD.<sup>3</sup> Patients who have a large proportion of small, dense low-density lipoprotein (LDL) cholesterol (pattern B) have a two- to threefold higher risk of developing CAD and angiographic progression.<sup>4</sup> Further, LDL pattern B and small HDL often coexist.<sup>5</sup> This study determined lipoprotein concentrations, sizes, and subclass levels among Asian Indians, and the results were compared with those from a predominantly Caucasian population from the Framingham Offspring Study.<sup>6</sup>

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This study was approved by the institutional review board of Bronx-Lebanon Hospital Center

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