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Drugs are not Enough: Metabolic Syndrome—A Call for Intensive Therapeutic Lifestyle Change

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Abstract

Whether intensive pharmacologic cardiovascular risk factor management reduces metabolic syndrome (MetSyn) prevalence is unknown. We compared the number of secondary prevention medications and ATP III defined MetSyn prevalence in coronary artery disease (CAD) patients entering cardiac rehabilitation from 1996-2001 (period 1, n=516) with those entering from 2002-2006 (period 2, n=609). Age, gender, and ethnicity were similar in both periods. From period 1 to period 2, participants took more secondary prevention medications (2.8+/-1.3 vs. 3.5+/-1.0, p<0.001). Prevalence of low HDL-cholesterol (66% vs. 66%), diabetes (37% vs. 38%), and hypertension (81% vs. 81%) were unchanged. The prevalence of hypertriglyceridemia decreased (48% vs. 36%, p<0.001), but the proportion meeting criteria for elevated waist circumference increased (51% vs. 58%, p<0.05), resulting in no change in overall MetSyn prevalence (60% vs. 59%, p=ns). More emphasis on therapeutic lifestyle change, in addition to intensive pharmacologic therapy, is needed to reduce MetSyn prevalence in CAD patients.

Introduction

The metabolic syndrome as defined by The National Cholesterol Education Program Adult Treatment Panel (ATP) III contains a collection of risk factors for cardiovascular disease including abdominal obesity, hypertriglyceridemia, low levels of high density lipoprotein cholesterol, elevated blood pressure, and hyperglycemia.1 The metabolic syndrome is highly prevalent among patients with coronary artery disease (CAD) entering cardiac rehabilitation (CR) programs with prevalence estimates ranging from 50-58%, twice that of the general population, and may be associated with increased cardiovascular risk.1-4 Although there has been controversy about the prognostic significance of the metabolic syndrome,5 a recent meta-analysis of 37 studies concluded that the metabolic syndrome is associated with increased risk for cardiovascular events even after adjusting for traditional cardiovascular risk factors and the individual components of the metabolic syndrome definition.6

Although not specifically targeted at the metabolic syndrome, recent guidelines have emphasized the benefit of intensive pharmacologic management of cardiovascular risk factors with medications such as anti-platelet agents, beta-blockers, statins, angiotensin-converting-enzyme inhibitors, and angiotensin receptor antagonists in addition to therapeutic lifestyle changes in patients with CAD.1,7-10 Despite increasing the number of medications and the intensity of therapy aimed at modifying cardiovascular risk in patients with CAD,11

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it is unknown whether these guideline recommendations have altered the prevalence of the metabolic syndrome or any of its components in patients with CAD.

Thus, the objective of this study is to compare the prevalence of the metabolic syndrome and its individual components among patients with CAD who were enrolled in CR during 2 different time periods (1996-2001 versus 2002-2006) and further, to determine whether there is any association between intensity of pharmacologic therapy and lifestyle interventions, as recommended by guidelines, and the prevalence of the metabolic syndrome or any of its individual components.

Methods

Study Population

A total of 1,125 patients with CAD have enrolled into our CR program since 1996. We divided these patients into 2 groups based on the patient's date of enrollment. A total of 516 patients enrolled between 1996 and 2001 (period 1) while ATP II guidelines were in effect, 12 and 609 patients enrolled between 2002 and 2006 (period 2), while ATP III guidelines were in effect.1 All patients who enrolled into the CR program are included in this analysis, regardless of whether they completed the program. At the time of enrollment into CR, we collect baseline demographic information as well as systolic and diastolic blood pressures, fasting lipid profile, waist circumference, body mass index, hemoglobin A1C (if diabetic), and assessments of diet and physical activity.

Metabolic Syndrome

We used a modified version of the ATP III definition of the metabolic syndrome, substituting a history of diabetes mellitus or the use of anti-diabetic medications for the glucose criterion, similar to that used in a previous publication in a CR population.3 Patients were classified as having the metabolic syndrome if they met any 3 of the following criteria at the time of their enrollment into CR: waist circumference > 40 inches in men or > 35 inches in women, triglycerides ≥ 150 mg/dL, high density lipoprotein cholesterol < 40 mg/dL in men or < 50 mg/dL in women, systolic blood pressure ≥ 130 mmHg or diastolic blood pressure ≥ 85 mmHg or history of hypertension, history of diabetes mellitus or taking anti-diabetic medications. History of hypertension and diabetes mellitus were reported by the patients at the time of enrollment and verified in the medical record.

We compared the prevalence of the metabolic syndrome as well as each of the individual components of the metabolic syndrome at CR entry between the 2 periods. In patients with metabolic syndrome at enrollment who completed CR, we also compared the percentage of patients who no longer met criteria for metabolic syndrome at CR completion between the two periods. For analyses involving the individual components, we included all patients for whom information on a given variable was available. Availability of data is summarized in Table 1. In our analyses of the overall prevalence of the metabolic syndrome in each period, we only included patients who had no missing data for any of the metabolic syndrome criteria.

Lifestyle Indices

All patients entering our CR program complete the MEDFICTS dietary assessment instrument at baseline, a dietary questionnaire which assesses adherence to national dietary recommendations,13,14 and complete an assessment of physical activity which yields self-reported "total metabolic hours" patterned after the 7-Day Physical Activity Recall questionnaire.15 Functional capacity is assessed by the 6 minute walk test. To standardize 6

minute walk data across age and gender subgroups, we used the % predicted distance achieved during the 6 minute walk test as our functional capacity measure.16,17

Medications for Secondary Prevention

Medication use is ascertained at CR entry and verified against the medical record. For each patient, we determined whether he/she was taking at least 1 medication from the following classes of medications for secondary prevention: aspirin, beta-blockers, anti-lipid agents, angiotensin-converting-enzyme inhibitor or angiotensin receptor blocker, and anti-diabetic agents. These data are summarized in a score ranging from 0 to 5 for each patient. Medication scores were then compared between the 2 periods.

Statistical Analyses

We used descriptive statistics such as means, standard deviations, frequencies, and percents to compare the prevalence of the metabolic syndrome, each of its individual components, the lifestyle indices, and the medication scores between the 2 periods. T-tests were used to compare continuous variables and chi-square was used for categorical data. To compare triglyceride levels and self-reported physical activity between the 2 groups, we used the Wilcoxon rank-sum test as these data were not normally distributed. For all analyses, a two-tailed alpha of 0.05 was used to determine statistical significance.

Results

The baseline characteristics of the patients entering our CR program during each of the enrollment periods are shown in table 2. Overall, the mean age of the patients entering CR was 60 with approximately one-third of the population women and one-third non-white during both periods. Compared with those enrolling during period 1, patients enrolling during period 2 had lower mean diastolic blood pressure, total cholesterol, low-density lipoprotein cholesterol, triglyceride, non-high density lipoprotein cholesterol, and hemoglobin A1C levels and a higher mean waist circumference. The most common referral diagnoses were myocardial infarction (34%), stable angina (31%), coronary artery bypass graft surgery (18%), and percutaneous coronary intervention (12%). There were no differences between the 2 periods in the distribution of referral diagnoses.

Metabolic Syndrome

Among patients who had data on all components of the metabolic syndrome, 611 (60%) met criteria for the metabolic syndrome at CR entry, and there was no difference in the prevalence of the metabolic syndrome between the 2 enrollment periods (60% in period 1 and 59% in period 2, p=NS). The number of metabolic syndrome components was also the same in both periods (2.8±1.3 in period 1 and 2, p=NS). Table 3 lists the proportion of patients meeting each of the individual components of the metabolic syndrome during the 2 enrollment periods. Patients in period 2 were less likely to meet criteria for hypertriglyceridemia (48% in period 1 and 36% in period 2, $p<0.001$) and more likely to meet criteria for elevated waist circumference (51% in period 1 and 58% in period 2, p=0.038).

Lifestyle Indices

Lifestyle indices were available on all patients entering CR and are summarized in table 2. Compared with period 1, patients enrolling into CR during period 2 had similar diet scores as assessed by the MEDFICTS questionnaire (33.3 +/- 29.7 in period 1 and 34.5 +/- 28.4 in period 2, p=NS). In terms of functional capacity and physical activity, patients in period 2 achieved similar % predicted distances on a 6 minute walk test (69% in period 1 and 71% in

period 2, p=NS) but had lower self-reported levels of physical activity (7.5 +/- 12.9 total metabolic hours in period 1 and 5.8 +/- 10.5 total metabolic hours in period 2, p=0.044) than patients in period 1. Among the 1,027 participants with complete data for the metabolic syndrome components, the median value reported for self reported physical activity was 2.0 total metabolic hours. Compared to individuals reporting < 2.0 total metabolic hours of physical activity, those reporting ≥ 2.0 total metabolic hours were less likely to meet criteria for metabolic syndrome, adjusting for age, gender, race, and diet as assessed by the MEDFICTS questionnaire (odds ratio 0.73, 95% confidence interval 0.57 - 0.95).

Medications for Secondary Prevention

Medications for secondary prevention were also available on all patients entering CR. Table 2 lists the differences between the 2 periods for each class of medication for secondary prevention. In each of the five classes, patients in period 2 were more likely to be prescribed a medication for secondary prevention than patients in period 1.

Change in Metabolic Syndrome Prevalence after CR

The focus of this study was to identify the prevalence of metabolic syndrome among patients enrolling in CR over time and explore for differences between earlier and later periods. However, we also examined if there were changes in the rates of metabolic syndrome from pre-to post-CR. In patients with metabolic syndrome at enrollment, 285 completed CR, 124 in period 1 and 161 in period 2. Overall, 19% no longer met ATP III criteria for metabolic syndrome at completion (p<0.001), and there was no difference in this reduction between enrollment periods (18% in period 1 and 20% in period 2, p=NS).

Discussion

In this analysis, patients enrolling in CR during period 2 were taking more medications for secondary prevention but had less physical activity and similar diets and functional capacity as compared to patients enrolling during period 1. Likely as a result of more intensive medical therapy, patients enrolling in CR during period 2 had lower mean diastolic blood pressure, total cholesterol, low-density lipoprotein cholesterol, triglyceride, non-high density lipoprotein cholesterol, and hemoglobin A1C levels. However, despite the more intensive pharmacologic management during period 2, the overall prevalence of the metabolic syndrome was the same during both enrollment periods (60% in period 1 and 59% in period 2, p=NS), as the reduction in the proportion of patients meeting metabolic syndrome criteria for hypertriglyceridemia during period 2 was offset by an increase in the percentage of patients with elevated waist circumference.

We observed an overall prevalence of 60% for the metabolic syndrome in patients entering CR from 1996-2006, twice the rate of the general population4 and comparable to what has been published previously in populations with CAD.2,3,18 Savage et al. reported an overall prevalence of 50% for the metabolic syndrome in 1,912 patients with CAD entering 2 northeastern United States CR programs between 1996 and 2003.3 Milani and Lavie observed a 58% prevalence for the metabolic syndrome in 235 patients with CAD who completed a CR program in Louisiana.2 Boden and others reported that 55% of the 2,287 patients with CAD who were enrolled in the Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation (COURAGE) trial, a study of medical therapy and percutaneous coronary intervention in patients with CAD, met criteria for the metabolic syndrome at the time of enrollment.18

The 2001 ATP III guidelines emphasized more intensive risk factor modification than the previous ATP II recommendations by lowering the triglyceride cut-points, raising the HDL

cut-points, recommending more intensive pharmacologic treatment of low density lipoprotein cholesterol, and identifying the metabolic syndrome as a secondary target of therapy.1 These recommendations were intensified further in 2004.7 As expected, given this emphasis on more intensive pharmacologic management of cardiovascular risk factors in patients with CAD, patients enrolling into CR during period 2 were prescribed more medications for secondary prevention than patients enrolling during period 1. Concurrent with this more intensive pharmacologic management, patients in period 2 had lower triglyceride and low density lipoprotein cholesterol levels, lower diastolic blood pressures, and were less likely to meet ATP III criteria for hypertriglyceridemia at CR entry. In contrast, patients in period 2 had similar diet scores and functional capacity, reported lower physical activity levels, and were more likely to have an elevated waist circumference than patients in period 1. As a result, there was no difference in the prevalence of the metabolic syndrome in these 2 groups at CR entry.

We hypothesize that during period 2, the increased utilization of medications for secondary prevention, especially the 43% increase in the proportion of patients taking anti-lipid medications, may be responsible for the reduction in the proportion of patients meeting ATP III criteria for hypertriglyceridemia at enrollment. However, individuals entering CR during period 2, despite having similar functional capacities and dietary intake, had greater waist circumferences and less self-reported physical activity than individuals entering during period 1. We hypothesize that because self-reported physical activity at CR entry was lower during period 2, the proportion of patients meeting ATP III criteria for central obesity increased, resulting in no net change in the prevalence of the metabolic syndrome at CR entry. This suggests that pharmacologic therapy, although essential in the modification of cardiovascular risk factors in patients with CAD, is insufficient to affect the prevalence of the metabolic syndrome in patients with CAD. More emphasis is needed on therapeutic lifestyle changes in addition to pharmacologic therapy in order to reduce the prevalence of the metabolic syndrome in patients with CAD. This is further supported by the observation that individuals reporting ≥ 2.0 total metabolic hours of self reported physical activity were less likely to meet criteria for metabolic syndrome than those reporting less than 2.0 total metabolic hours, adjusting for age, gender, race, and dietary intake.

Although outcome evaluation was not the intent of this study, we were interested to find that CR was associated with an average 19% reduction for metabolic syndrome across both time periods. We relied upon a previous history of diabetes mellitus or use of anti-diabetic medications for our glucose criterion and include a history of hypertension in our blood pressure criterion. Because a history of diabetes mellitus and history of hypertension are “fixed” metabolic syndrome criteria which cannot be eliminated as metabolic syndrome criteria, we have likely underestimated the true benefit of CR in patients with metabolic syndrome. Milani and Lavie2 as well as Gayda et al.,19 who used fasting glucoses rather than a history of diabetes for their glucose criterion, observed a 37% and 31% reduction for metabolic syndrome in CAD patients completing CR, respectively. Because less than one-quarter of eligible patients attend CR,20-23 these large reductions in prevalence of metabolic syndrome observed over the relatively short duration of CR underscore the importance of physician emphasis on therapeutic lifestyle changes and participation in supervised behavioral modification programs like CR.

Our study has a number of limitations. The study design is cross-sectional in nature and can thus not establish any causal relationship between the associations observed. As a result, we are unable to establish that the increase in the number of medications taken for secondary prevention during period 2 caused the observed decrease in the proportion of patients who met ATP III criteria for hypertriglceridemia. We did observe, however, that the patients in period 2 had similar diets and less physical activity than patients in period 1. As a result, a

change in lifestyle between the 2 periods does not seem to be a plausible explanation for the reduction in hypertriglyceridemia during period 2. Further studies will be necessary to evaluate our hypothesis that more intensive drug therapy, especially anti-lipid therapy, is likely responsible for this reduction in triglycerides. Second, our population represents only patients entering CR with established diagnoses of CAD. Extrapolation of these observations to patients with CAD who are not enrolled in CR programs or to populations without established CAD may not be valid. Third, these data come from a single CR program and may not be representative of other CR settings, although the overall prevalence of the metabolic syndrome in our patient population is very similar to published data from CR programs in other regions of the United States. Fourth, in 1997 the American Diabetes Association updated the definition of diabetes. Most significantly, they lowered the threshold value of fasting plasma glucose used to define diabetes to 126 mg/dL.24 Because we substituted history of diabetes or use of anti-diabetic medications for the glucose criterion, this change in definition may have affected our prevalence estimates for diabetes. Individuals enrolling in CR prior to this change may have met the new diabetes criteria, slightly reducing the proportion with a documented history of diabetes prior to 1997. However, since this only affects the first year of our study, we do not believe our values for diabetes prevalence are significantly limited by this change in definition. Fifth, more participants were missing lipid values during period 1 than period 2. However, those participants with missing lipid values in period 1 did not differ significantly by age, gender, ethnicity, body mass index, waist circumference, prevalent diabetes, lifestyle, or pharmacologic therapy from enrollees in period 1 who were not missing lipid values. Sixth, we do not know the duration of medication use prior to entering CR. Medications do not affect a history of blood pressure or diabetes, the waist circumference, or HDL levels by any significant degree. However, anti-lipid medications, which were primarily statins, begun just prior to CR referral in period 2 may not have fully reduced triglyceride levels by enrollment into CR. To address this issue, we performed a “worst-case scenario” sensitivity analysis with the following assumptions: 1) all patients in period 2 with a referral diagnosis of myocardial infarction, coronary artery bypass graft surgery, or percutaneous coronary intervention had 30% lower triglycerides as a result of newly initiated statin therapy, and 2) none of the corresponding patients in group 1 had any medication effect on their triglyceride level. Based on these assumptions, the differences between the groups remained non-significant with the metabolic syndrome prevalences of 60% in period 1 and 55% in period 2. Thus our lack of knowledge about duration of medical therapy most likely did not affect our findings.

Metabolic syndrome remains highly prevalent in CR participants despite intense pharmacologic management of cardiovascular risk factors. More emphasis on therapeutic lifestyle changes, including CR, which have been shown to improve metabolic parameters and reduce the prevalence of metabolic syndrome,2،19،25-31 is necessary, in addition to intensive pharmacologic therapy, to alter the prevalence of metabolic syndrome in patients with CAD.

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Table I

Number and Percent of Available Data for each of the Metabolic Syndrome Components During Period 1 (1996-2001) and Period 2 (2002-2006)

	Period 1 (N=516)	Period 2 (N=609)	P value
Waist circumference	505 (98)	603 (99)	NS
Triglycerides	467 (91)	586 (96)	<0.001
HDL-C	463 (90)	590 (97)	<0.001
Hypertension	516 (100)	607 (99)	NS
Diabetes	516 (100)	609 (100)	NS
Have no missing data for any criteria	446 (86)	581 (95)	<0.001

HDL-C = high density lipoprotein cholesterol

Table II

Baseline Demographics and Clinical Characteristics for the Entire Population During Period 1 (1996-2001) and Period 2 (2002-2006)

	Period 1 (N=516)	Period 2 (N=609)	P value
Age (years)	60 (11.3)	61 (11.1)	NS
Women	33%	32%	NS
Non-white	32%	35%	NS
Blood Pressure (mmHg)	121.7 (20.6)	120.9 (18.1)	NS
Systolic Blood Pressure			
Diastolic Blood Pressure	72.8 (11.5)	70.2 (11.1)	<0.001
Lipid Profile	189.9 (48.1)	172.9 (42.5)	<0.001
Total Cholesterol (mg/dL)			
LDL-C (mg/dL)	115.3 (41.0)	107.5 (37.2)	0.002
HDL-C (mg/dL)	40.6 (12.9)	40.2 (12.2)	NS
Triglycerides (mg/dL)	183.1 (186.1)	152.9 (120.1)	<0.001*
Non-HDL-C (mg/dL)	148.5 (46.1)	132.7 (40.7)	<0.001
Waist Circumference (inches)	40.0 (6.2)	40.8 (6.6)	0.026
Body Mass Index (kg/m2)	30.6 (6.9)	30.8 (7.2)	NS
HbA1C (diabetics only)	7.7 (1.8)	6.9 (2.5)	<0.001
Lifestyle Indices	33.3 (29.7)	34.5 (28.4)	NS
MEDFICTS score			
%predicted 6 min walk	69%	71%	NS
Physical activity (totmethrs)	7.5 (12.9)	5.8 (10.5)	0.044*
Current Smoker	21%	20%	NS
Secondary Prevention Medications	2.8 (1.3)	3.5 (1.0)	<0.001
Total**			
Aspirin	83%	89%	0.005
Beta-blocker	57%	75%	<0.001
Anti-lipid agent	58%	84%	<0.001
ACE-I / ARB	52%	71%	<0.001
Anti-diabetic agent	25%	31%	0.026

All values expressed as mean (SD) or %.

* Analyzed using the Wilcoxon rank-sum test as the distributions of each of these variables were skewed.

** Secondary prevention medications (aspirin, angiotensin-converting-enzyme inhibitor or angiotensin receptor blocker, beta-blocker, lipid-lowering agents, and anti-diabetic agents) were counted (1 point per medication class, maximum score of 5).

ACE-I = angiotensin-converting-enzyme inhibitor, ARB = angiotensin receptor blocker, HbA1C = hemoglobin A1C, HDL-C = high density lipoprotein cholesterol, LDL-C = low density lipoprotein cholesterol, non-HDL-C = non-HDL cholesterol, totmethrs = total metabolic hours

Table III

Percent of Patients Meeting Criteria for Metabolic Syndrome and its Individual Components Among Those with Available Data on These Components During Period 1 (1996-2001) and Period 2 (2002-2006).*

	Period 1	Period 2	P value
Increased waist circumference	51	58	0.038
Low HDL-C	66	66	NS
Hypertriglyceridemia	48	36	<0.001
Hyperglycemia	37	38	NS
Elevated blood pressure	81	81	NS
Overall metabolic syndrome	60	59	NS

HDL-C = high density lipoprotein cholesterol

* Number of patients with available data for each of these components listed in Table I.