All-cause Mortality Associated with Specific Combinations of the Metabolic Syndrome According to Recent Definitions

Received for publication 30 January 2007 and accepted in revised form 5 June 2007.

Running title: Mortality and MetS components

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ABSTRACT

Objective: The aim was to evaluate the impact of specific component combinations of the metabolic syndrome (MetS) on all-cause mortality risk in a large French cohort.

Research Design and Methods: The population was composed of 39,998 (52.6±8.3 years) men and 20,756 (54.7±9.2 years) women, examined at the IPC Center from 1999 to 2002. Mean follow-up was 3.57±1.12 years. MetS was defined according to three definitions: the National Cholesterol Educational Program (NCEP 2001), the revised NCEP (NCEP-R, AHA/NHLBI 2005), and the International Diabetes Federation (IDF 2005). Subjects with MetS were compared to subjects without MetS, and to subjects with no MetS components, using Cox regression models.

Results: The prevalence of MetS increased from 10.3% (NCEP) to 17.7% (NCEP-R) and 23.4% (IDF). After adjustment for age, gender, classical risk factors and socioprofessional categories, and compared to subjects without MetS, the risk of all-cause mortality was 1.79 (1.35-2.38), 1.46 (1.14-1.88) and 1.32 (1.04-1.67) with the NCEP, NCEP-R and IDF definitions, respectively. Among the combinations significantly associated with all-cause mortality, the following three-component combinations and four-component combination were more highly significant than other combinations (p<0.05): elevated waist circumference plus elevated glucose, plus either elevated blood pressure or elevated triglycerides, and the combination of all four of these.

Conclusions: In a large middle-aged French population, four specific components of MetS are associated with a much higher mortality risk. These results may have a significant impact on detecting ‘high risk’ subjects suffering from metabolic disorders and underline the fact that MetS is a non-homogeneous syndrome.
Described by Reaven in 1988 (1), the metabolic syndrome (MetS), defined as a constellation of several cardiometabolic risk factors, has been the focal point of a large number of studies which have attempted to elucidate the pathophysiological and epidemiological aspects of this syndrome.

Recently, several expert groups have developed simple diagnostic criteria to be used in clinical practice to identify subjects with a MetS profile (2). Until very recently, the principle definitions used to define MetS were those established by the World Health Organisation (WHO) and the third report of the National Cholesterol Educational Program’s Adult Treatment Panel (NCEP) (3). Because criteria included in the NCEP definition could easily be recorded, a large number of studies used this definition when examining different epidemiological aspects of MetS.

New criteria for identifying subjects with MetS were published in 2005 by the International Diabetes Federation (IDF) (4), and by the American Heart Association and the National Heart, Lung, and Blood Institute (AHA/NHLBI) [revised NCEP definition (NCEP-R)] (2). The IDF definition, which requires abdominal obesity as one of the criteria for identifying subjects with MetS, is in agreement with findings from studies which have shown the prognostic importance of the association of overweight and other cardiometabolic risk factors (5, 6).

The existing definitions are based on different expert opinions, but few longitudinal epidemiological studies have shown the impact of all these classifications on mortality. Recently, a few studies have suggested that the IDF definition is either similar to the NCEP for women over 60 years of age with coronary heart disease (CHD) (7), or not associated to CHD mortality and morbidity in a Chinese population (8), or similar to the NCEP and NCEP-R definitions for the impact on all-cause mortality (9) or cardiovascular mortality in European men but not in women (10).

The required presence of three out of the five MetS components in order to establish a diagnosis of MetS is the common feature of these three classifications. Using these definitions, many studies have shown that MetS is associated with an excess risk of all-cause and cardiovascular disease (CVD) mortality (11). Two meta-analyses which included all of these studies recently summarized the relationship between MetS and mortality (12, 13). However, the impact of MetS varies greatly from one study to the next. This variation could be due to population characteristics, the definition used, and length of follow-up.

Interestingly, to date, no study has clearly shown whether the risk of mortality is similar for the different component combinations of MetS, although some have suggested that the impact of specific associations could be particularly deleterious (14, 15). It appears that specific associations are more highly linked to cardiovascular morbidity than others (16), especially those associated with metabolic disorders in diabetics (17). Grundy et al. (2) showed that MetS is still not clearly defined and that the role of each component as a predictor of mortality has not been clearly established.

The primary objective of this study was to address the impact of different three-component and four-component combinations of MetS according to the NCEP, NCEP-R and IDF definitions on all-cause mortality in a large French population composed of 60,754 men and women.

RESEARCH DESIGN AND METHODS

Population

Subjects were examined at the IPC (Investigations Préventives et Cliniques) Center (Paris-France). This medical center, which is subsidized by the French national health care system (Sécurité Sociale-CNAMTS), offers all working and retired individuals and their families a free medical examination every five years. It is one of the largest medical centers of this kind in France, carrying out approximately 25 thousand health examinations per year for people living in the Paris area.

Our study population was composed of 39,998 (52.6±8.3 years) men and 20,756 (54.7±9.2 years) women, aged 40 years and over,
who had a health checkup at the IPC Center between January 1999 and December 2002. In order to focus on primary prevention, subjects with previous cardiovascular disease were excluded.

Supine blood pressure (BP) was measured in the right arm using a manual mercury sphygmomanometer, after a 10-minute-rest period. The first and the fifth Korotkoff phases were used to define systolic blood pressure (SBP) and diastolic blood pressure (DBP). The mean of three measurements was considered as the BP value. Waist circumference was measured using an inelastic tape placed midway between the lower ribs and iliac crests on the mid-axillary line. Standard biological parameters (enzymatic method, automat HITACHI 917; colorimetric method for albumin dosage and hematology: ABX, Pentra 120) were measured under fasting conditions; HDL cholesterol was measured by direct enzymatic array with cyclo-dextrin. A resting electrocardiogram was recorded. Tobacco consumption (never smoker, ex-smoker and current smoker), physical activity (regular physical activity: yes or no), personal medical history, current medications and alcohol consumption were assessed using a self-administered questionnaire. All clinical and biological parameters were evaluated on the same day of the examination.

The IPC Center received authorization from the Comité National d’Informatique et des Libertés (CNIL) to conduct these analyses. All subjects gave their informed consent at the time of the examination.

**Follow-up**

For each screened subject, vital status was obtained from the French National Institute of Statistics and Economic Studies (Institut National de Statistiques et d’Etudes Economiques, INSEE, France). To validate this procedure, we took a random sample of 250 subjects and compared our data with those found in city hall registries. A discordance was found in only two cases (<1%). Based on the results of this validation, we considered that we had a complete follow-up for the entire study population.

The study population was followed up until March 2004; the mean follow-up was 3.6 ±1.1 years. During this period, 0.68% (n=271) of men and 0.42% (n=87) of women died.

**Data analyses**

**Definitions**

Three different definitions of MetS were used to evaluate the impact on mortality. The first definition was the NCEP-ATP III (2001) (NCEP definition) (3), which requires at least three of the following criteria:

- waist circumference > 102 cm in men and > 88 cm in women (W)
- triglycerides ≥150 mg/dl (TG)
- HDL cholesterol < 40 mg/dl in men and < 50 mg/dl in women (HDL)
- SBP ≥ 130 mmHg or DBP ≥ 85 mmHg (SBP)
- fasting glucose ≥ 110 mg/dl (G)

The second definition was the AHA/NHLBI 2005 (NCEP-R definition) (2), which requires at least three of the following criteria:

- waist circumference ≥ 102 cm in men and ≥ 88 cm in women (W)
- triglycerides ≥150 mg/dl or a specific treatment for elevated triglycerides (TG)
- HDL cholesterol < 40 mg/dl in men and < 50 mg/dl in women or a specific treatment for reduced HDL-C (HDL)
- SBP ≥ 130 mmHg or DBP ≥ 85 mmHg or antihypertensive treatment (SBP)
- fasting glucose ≥ 100 mg/dl or drug treatment for elevated glucose (G)

The third definition (IDF definition) (4) requires the presence of abdominal obesity defined as waist circumference ≥ 94 cm in men and ≥ 80 cm in women for Europids (W), and at least two of the following criteria:

- triglycerides ≥150 mg/l or a specific treatment for lipid abnormalities (TG)
- HDL cholesterol < 40 mg/dl in men and < 50 mg/dl in women or a specific treatment for lipid abnormalities (HDL)
- SBP ≥ 130 mmHg or DBP ≥ 85 mmHg or antihypertensive treatment (SBP)
- fasting glucose ≥ 100 mg/dl or diabetes (G)
**Statistical Analyses**

Descriptive analyses were carried out separately in men and women. As the relationship between MetS and all-cause mortality was similar in both genders (p for interaction=0.70), all subjects were grouped together for mortality analyses. The impact of MetS on all-cause mortality was studied using Cox regression analysis including age, gender, current smoking status, LDL cholesterol levels, declared physical activity and socioprofessional category in the second model. Cox regression models were used to assess the risk [Hazard Ratio (HR) and 95% confidence interval] of all-cause mortality in the presence of MetS and its components: at least three of the five MetS components on all-cause mortality was evaluated.

Three different analyses were conducted in order to clarify the relationship between all-cause mortality and MetS, MetS’s components, and specific associations of at least three MetS components. The impact of MetS on all-cause mortality was evaluated by comparison to the reference group which was defined as subjects without MetS (≤ 2 MetS components). Mortality associated with each MetS component and combinations of these components (2,3,4) was compared to the group with no MetS components. All-cause mortality associated with specific combinations of three or four components was compared with other subjects with MetS defined without these components.

All statistical analyses were carried out using the SAS statistical software package (version 8.02) [SAS institute, Cary, North Carolina, USA].

**RESULTS**

Mean age was 52.6±8.3 years in men and 54.7±9.2 years in women. The percentage of subjects who had a regular physical activity was 47.3% and 45.7% respectively in men and women. The percentage of current smokers and never smokers was 26.9% and 41.6% respectively in men, and 17.8% and 67.0% respectively in women. In this population, 42.5% of the men and 15.5% of the women were “white-collar” workers. Mean LDL cholesterol was 1.42±0.35 g/l in men and 1.32±0.36 g/l in women.

The baseline age for subjects who died during follow-up was 57.0±9.7 years for men and 62.7±10.1 years for women versus 52.5±8.3 years for men and 54.7±9.2 years for women among survivors (p<0.0001). Mean age at death was 59.1±9.7 years for men and 64.7±10.0 years for women versus mean age at the end of the follow-up period for survivors which was 56.1±8.4 years and 58.3±9.3 years, respectively. After adjustment for age, a number of variables differed significantly between subjects who had died during the follow-up period and those who had not. Subjects (both men and women) who had died had higher blood pressure, pulse pressure, heart rate, alcohol and tobacco consumption, prevalence of hypertension, obesity and diabetes, and test scores for stress and depression (p<0.01). Men who had died also had less physical activity (data not shown).

The prevalence of MetS according to the IDF, NCEP-R and NCEP definitions was, respectively 26.0% (n=10,412), 20.0% (n=7981) and 11.7% (n=4671) in men, and 18.4% (n=3814), 13.5% (n=2793) and 7.5% (n=1560) in women. Regardless of the definition used, the prevalence of MetS was higher among men than among women and increased with age (data not shown). The prevalence of each MetS component and combinations of two components is shown in Table 1. Regardless of the definition, elevated blood pressure was the most prevalent MetS component. The least prevalent was reduced HDL cholesterol. Taking into account the different thresholds, the component for which the greatest difference was found between the three definitions was increased glycemia which represented 13% of the subjects with the NCEP and 39.2% with the NCEP-R and IDF.

When compared to subjects with no MetS (≤ 2 MetS components) after adjustment for age, gender, current smoking status, LDL-cholesterol, declared physical activity and socioprofessional category, the risk of all-cause mortality associated with the presence of MetS was [Hazard Ratio (HR) and 95% CI]: 1.79 (1.35-2.38), 1.46 (1.14-1.88) and 1.32 (1.04-1.67) for the NCEP, NCEP-R and IDF definitions, respectively.
Regardless of the definition, the presence of only one component was not significantly associated with increased risk of all-cause mortality during the 3.5-year follow-up. Among combinations of two MetS components, BP+W, BP+G and W+TG were significantly associated with an increased risk of all-cause mortality for the NCEP and NCEP-R definitions. The W+G combination was significantly associated with an increased risk of all-cause mortality for the NCEP and IDF definitions. BP+W, BP+G, W+G and W+TG were significantly associated with an increased risk of all-cause mortality for the NCEP definition, as were BP+W, BP+G and W+TG for the NCEP-R definition. The only combination significantly associated with an increased risk of all-cause mortality for the IDF definition was W+G.

Figure 1 shows the all-cause mortality risk associated with different combinations of at least three MetS components according to the three different definitions, compared to subjects with no MetS components, after adjustment for age, gender, current smoking status, LDL cholesterol, declared physical activity and socioprofessional category. The number of subjects per combination, and the percentage of subjects with strictly three components in each group are shown in this figure. For all three definitions, subjects who had combinations of W+G, plus BP or TG, regardless of the additional MetS components, had a statistically significant higher risk of all-cause mortality than subjects with no MetS components. A statistically significant high risk of all-cause mortality was also found for the following associations: TG+BP+G, W+TG+BP for the NCEP definition, TG+HDL+G for the NCEP-R definition, and W+TG+BP for the IDF definition. For all three definitions, only one four-component combination of MetS (W+TG+G+BP) was associated with a significant increase in all-cause mortality risk by comparison to subjects with no MetS components, regardless of the additional MetS components involved: HR (95% CI) was 2.08 (1.17-3.67) for the NCEP definition, 1.82 (1.16-2.82) for the NCEP-R definition and 1.55 (1.05-2.27) for the IDF definition.

CONCLUSIONS

Influence of the MetS definition on prevalence

Our results, obtained from a large French population, confirm the impact of the choice of the definition used to identify MetS on its prevalence. Regardless of the definition, the prevalence found in France was lower than in North America and in other European countries; it varied from 11.7% in men and 7.5% in women according to the NCEP definition, to 26.2% in men and 18.0% in women according to the IDF definition. This discrepancy was already noted in the MONICA study (18), in a French population. The NCEP-R definition remains intermediary, as in other studies (9). Clearly, prevalence increases approximately 50% when the IDF definition is used as compared to the NCEP definition. In addition, Lorenzo et al. (19) compared the prevalence in different populations and showed that the impact of the different definitions on prevalence might depend on the characteristics of the population studied.

Relationship between MetS, as defined by the different definitions, and mortality

Numerous studies have shown the increased risk of all-cause mortality and cardiovascular mortality associated with MetS; the risk is nearly two times higher than without MetS (11, 20-30).

In a recent study we showed that MetS was characterized by altered levels of clinical and biological characteristics known as cardiovascular risk markers or risk factors (31). One point of interest of the present analysis is that despite a shorter follow-up period than in other studies, the impact of MetS on all-cause mortality was confirmed with similar intensity. Another point is
that the results observed in the present study showed a higher risk of all-cause mortality with the NCEP 2001 definition compared to the other two definitions, confirming the results found by Katzmarzyk et al. (9), Lawlor et al. (7), Wang et al. (8).

The interest of specific component combinations

The most important result of this study is that the risk of short-term all-cause mortality among subjects with MetS is different depending on the components involved.

As shown in figure 1, by comparison with subjects without MetS components, not all combinations are associated with the risk of all-cause mortality. W+ G+ BP or TG, regardless of the definition, and TG+BP+G, W+TG+BP for the NCEP definition, TG+HDL+G for the NCEP-R definition, and W+TG+BP for the IDF definition are associated with short-term mortality risk.

When compared with other associations of MetS components, MetS defined by the presence of high waist circumference, high glucose levels, and high triglycerides and/or high blood pressure was significantly associated with a high risk of all-cause mortality regardless of the other additional MetS component(s) involved. This result was observed for all definitions.

Few studies have evaluated the effect of specific combinations of risk factors on morbidity and mortality. Wilson et al. (16), using the Framingham offspring study data, after evaluation of the different combinations of MetS components, found that few differences in impact on incidence of CVD and Type 2 diabetes were present between associations of three components. The difference observed between that study and the present report could be explained by the characteristics of the population, the definition of MetS and the nature of analyzed events. The Framingham population was characterized by a higher prevalence of elevated waist circumference and a higher prevalence of reduced HDL-cholesterol. Furthermore, the threshold for elevated glucose levels varied from 110 mg/dl in our study to 100 mg/dl in the study by Wilson et al. (16). Lemieux et al. (14) suggested that simultaneous measurement of waist circumference and fasting triglycerides contributed to a better identification of high risk patients. In their analysis, Katzmarzyk et al. (9) observed a significant increase in CVD mortality when elevated waist circumference was associated with two or three risk factors. Protopsaltis et al. (17) showed that in diabetics without known CHD, the triad consisting of diabetes, hypertension, and low HDL, or the combination of diabetes, hypertension, low HDL and high TG levels was associated with greater risks of developing a CHD event. In a previous study, we reported that subjects with impaired fasting glucose presented an elevated risk of cardiovascular mortality and all-cause mortality when associated with elevated SBP (32). Our results suggest that MetS is not a homogenous syndrome, from a pathophysiological standpoint. Focussing on determining a more accurate definition of MetS, based on robust clinical outcomes, appears necessary. Interestingly, the three highest risk combinations are based on the consequences of increased deposit of abdominal fat which is undoubtedly the primary factor involved in the underlying mechanism of MetS. The relationship between MetS and abdominal obesity appears to play a critical role in the clinical consequences of MetS in terms of insulin resistance and inflammation (33). Different links between visceral adipose tissue metabolism, its secreted factors and mortality are now major fields of research.

The findings of this study require further confirmation in other populations, based on geographic origin, lifestyle, underlying diseases and different global mortality risk. These findings, however, do clearly indicate that MetS needs to be more clearly defined and that attention should be focused on the combination of factors which are mostly associated with short- and long-term mortality risk.

Limitations of the study

The study population was composed of volunteers for a standard health checkup. The fact that these individuals were volunteers suggests that they were particularly concerned about their
health and consequently their health-related behavior. This could explain the low prevalence of MetS found among this particular population. In the cohort from the French population-based study MONICA, the prevalence of MetS was higher: 22.5% in men and 16.5% in women, for the 3441 subjects included (16). Similar data were already found in the large French DESIR study (34). Our data however, according to the NCEP definition, are similar to those from the DESIR study and to a somewhat lesser degree to the MONICA study, which regroups three French geographical regions and is more representative of France. However, the strength of the association between MetS and all-cause mortality was similar to the one which was observed in other populations, suggesting a representative characteristic of MetS in our population. As is common practice in the majority of epidemiological studies, the classification of MetS was established using a single measure for each parameter and diagnosis of MetS was not confirmed with another evaluation. During this short follow-up, we were not able to show any difference in the relationship between MetS and all-cause mortality, based on gender, as was recently mentioned in two meta-analyses (11,12). The duration of the study was undoubtedly not long enough to observe significant differences.

Because the follow-up period was short and the number of deaths relatively low, an analysis which would take into account causes of mortality, particularly CVD and CHD mortality, was not carried out.

In conclusion, in a French middle-aged population, the presence of MetS identified using all three definitions was associated with an excess risk of all-cause mortality after less than four years of follow-up. Among all the possible three-component and four-component combinations, three were significantly more highly associated with all-cause mortality; all of these associations included increased abdominal fat deposit assessed by waist circumference, and increased glycemia with or without increased blood pressure. This main result suggests the heterogeneity of MetS regarding short-term all-cause mortality.

These results have a strong impact on identifying a category of ‘high risk’ subjects suffering from metabolic disorders and on preventing short-term increase in all-cause mortality through the use of dedicated intervention strategies.

ACKNOWLEDGMENTS

This study was made possible with the help of the Caisse Nationale d’Assurance Maladie (CNAM), the Caisse Primaire d’Assurance Maladie de Paris (CPAM-Paris) and the Institut National de la Santé et de la Recherche Médicale (INSERM), Paris.
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Table I: Number and prevalence (%) of one MetS component, two MetS components, and MetS according to the three definitions: NCEP, NCEP-R, IDF

<table>
<thead>
<tr>
<th>Definition</th>
<th>NCEP</th>
<th>NCEP-R</th>
<th>IDF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td><strong>One component</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elevated BP</td>
<td>37137 (61.1%)</td>
<td>37652 (62.0%)</td>
<td>37652 (62.0%)</td>
</tr>
<tr>
<td>Elevated W</td>
<td>9461 (15.6%)</td>
<td>9461 (15.6%)</td>
<td>25796 (42.5%)</td>
</tr>
<tr>
<td>Elevated TG</td>
<td>9614 (15.8%)</td>
<td>13559 (22.3%)</td>
<td>13559 (22.3%)</td>
</tr>
<tr>
<td>Reduced HDL C</td>
<td>4836 (8.0%)</td>
<td>4836 (8.0%)</td>
<td>4836 (8.0%)</td>
</tr>
<tr>
<td>Elevated G</td>
<td>7924 (13.0%)</td>
<td>23818 (39.2%)</td>
<td>23818 (39.2%)</td>
</tr>
<tr>
<td><strong>Two components</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP+W</td>
<td>7141 (11.8%)</td>
<td>7706 (12.7%)</td>
<td>19222 (31.6%)</td>
</tr>
<tr>
<td>BP+TG</td>
<td>7237 (11.9%)</td>
<td>10126 (16.7%)</td>
<td>10126 (16.7%)</td>
</tr>
<tr>
<td>BP+HDL</td>
<td>3115 (5.1%)</td>
<td>3176 (5.2%)</td>
<td>3176 (5.2%)</td>
</tr>
<tr>
<td>BP+G</td>
<td>6164 (10.2%)</td>
<td>6250 (10.3%)</td>
<td>6250 (10.3%)</td>
</tr>
<tr>
<td>W+TG</td>
<td>2871 (4.7%)</td>
<td>2871 (4.7%)</td>
<td>8335 (13.7%)</td>
</tr>
<tr>
<td>W+HDL</td>
<td>1550 (2.6%)</td>
<td>1540 (2.5%)</td>
<td>3146 (5.2%)</td>
</tr>
<tr>
<td>W+G</td>
<td>2265 (3.7%)</td>
<td>5019 (8.3%)</td>
<td>12263 (20.2%)</td>
</tr>
<tr>
<td>TG+HDL</td>
<td>2243 (3.7%)</td>
<td>2429 (4.0%)</td>
<td>2429 (4.0%)</td>
</tr>
<tr>
<td>TG+G</td>
<td>2311 (3.8%)</td>
<td>6984 (11.5%)</td>
<td>6984 (11.5%)</td>
</tr>
<tr>
<td>HDL+G</td>
<td>964 (1.6%)</td>
<td>2236 (3.7%)</td>
<td>2236 (3.7%)</td>
</tr>
<tr>
<td><strong>MetS (≥3 components)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6231 (10.3%)</td>
<td>10,774 (17.7)</td>
<td>14,226 (23.4%)</td>
</tr>
</tbody>
</table>

Abbrev.: BP: increased blood pressure, W: increased waist circumference, TG: increased triglycerides, HDL C: reduced HDL cholesterol, G: increased glycemia.
Figure legend
Figure 1: Hazard ratio (95% CI) for all-cause mortality, adjusted for age, gender, current smoking status, LDL cholesterol levels, declared physical activity and socioprofessional category associated with the presence of three-component combinations of MetS according to the three definitions: A: NCEP, B: NCEP-R, C: IDF. The columns depict the number of subjects included in each subgroup, and the percentage of subjects with strictly three components. The reference group is composed of subjects with no MetS components.
Figure 1

A:

- TG+HDL+G 603 11.3%
- W+TG+HDL 837 13.0%
- HDL+BP+G 765 18.6%
- TG+HDL+BP 1607 42.7%

B:

- W+BP+G 4271 47.8%
- HDL+BP+G 1662 22.7%
- TG+HDL+BP 1746 26.4%

C:

- W+BP+G 9777 55.5%
- W+TG+BP 6721 34.2%
- W+TG+HDL 1748 12.5%
- W+HDL+BP 2299 21.4%