

Original Research

ROmanian Multicentric Study of the Prevalence of METabolic Syndrome – ROMES

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Introduction: The metabolic syndrome (MetS) is an entity with a high and continuously increasing prevalence in the modern world. It is of great importance to have actual data about its prevalence. The aim of this study was to assess the prevalence of MetS in a selected population (i.e. patients from cardiology departments) using both NCEP ATP-III and IDF criteria. Secondary objectives were to evaluate the correlation of MetS and abdominal obesity with specific cardiovascular pathology, and to compare the prevalence of MetS according to the two definitions.

Method: This was a cross-sectional study developed in two parts: the pilot study evaluated all patients admitted to 12 cardiology departments of county hospitals, and the main study included 1176 patients in 15 cardiology departments.

Results: The prevalence of MetS in the pilot study (1326 patients, 53.4% men), using only NCEP ATP-III criteria, was 42.8% (45.9% in men and 39.4% in women, $p=0.01$), while in the main study (1176 patients, 49.7% men) the prevalence of MetS according to NCEP ATP-III and to IDF criteria was 40.6% (38.3% in men and 42.3% in women) and 44.2% (43.1% in men and 45.3% in women), respectively. MetS represented a risk factor only for stable angina (RR=1.35, 95% CI=1.20-1.53, $p<0.001$), with no gender difference.

Conclusions: The prevalence of MetS and abdominal obesity is high in a population with cardiovascular disease. Both classifications showed a slightly higher prevalence of MetS in women compared to men. The relative risk of coronary heart disease associated with MetS was statistically significant only for stable angina.

The metabolic syndrome (MetS) is a clinical and biological entity of lipid and non-lipid factors of metabolic origin, associated with insulin resistance, that places subjects at risk for cardiovascular and cerebrovascular events. It has been previously defined by the 3rd Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (NCEP ATP-III), which suggests that the diagnosis should be made when at least three of the following characteristics are present: high fasting blood glucose, high blood pressure,

low HDL cholesterol, high triglycerides, and abdominal obesity.¹ Recently, the International Diabetes Federation (IDF) statement² reviewed the criteria for MetS and defined it as central obesity plus two of the four remaining factors described above.³ Moreover, additional metabolic measurements have been extensively studied in relation to MetS in an attempt to improve the definition.

The prevalence of metabolic syndrome is high and is continuously increasing in the modern world.⁴⁻⁷ Previous surveys, using the NCEP ATP-III criteria, have reported an estimated prevalence of 24% in

the general population over the age of 20 years, increasing from 6% in the 20-29 year age group to over 40% in subjects aged 60 years and over.^{8,9} In a selected population study (i.e. diabetic subjects), using the same criteria, a prevalence of 86% for MetS was reported.

On the other hand, the presence of MetS is associated with a twofold relative risk for a subsequent cardiovascular event and a fivefold relative risk for the development of type 2 diabetes mellitus.^{10,11} Moreover, other studies have shown that cardiovascular mortality is 45% higher in men and 73% higher in women with MetS compared to those without. A recent Japanese study showed that MetS, diagnosed according to different definitions, is associated not only with an increased incidence of coronary artery disease, but also with extensive coronary artery disease.¹² This is the reason why early diagnosis and correction of risk factors are important.

To our knowledge, to date no MetS prevalence studies have been carried out in our country (Romania). We started these studies in a hospital-based population to obtain a preliminary estimation of MetS prevalence and to encourage the health authorities to extend the research to the general population.

The main objective of our research was to determine the prevalence of MetS and abdominal obesity in a selected population, i.e. patients with cardiovascular diseases. Secondary objectives were the correlation of cardiovascular diseases with the presence of metabolic syndrome and abdominal obesity, and to

compare the prevalence of MetS as assessed by both NCEP ATP-III and IDF criteria.

Methods

Patients

Our study was designed as a cross-sectional study and was developed in two parts. The pilot study was organised on November 3, 2005, in 12 different cardiology departments in county hospitals (Table 1). All adult patients admitted to these departments were eligible for the study. A questionnaire-based interview was carried out with 1326 in-hospital patients (53.4% men). The presence of MetS was evaluated irrespectively of the patients' age. A second screening, the main study, was started after the pilot study analysis and included a large number of patients with more refined data related to classical and newly described risk factors, as well as cardiovascular pathology. Fifteen centres participated in this screening (Table 1) with 1176 patients (49.7% men, age 21-93 years, mean age 61.4 ± 11.1 years). We used the same screening methodology, but a more complex questionnaire, in order to obtain data for in-hospital patients on Nov 24, 2005.

According to the ATP-III criteria, MetS was diagnosed when at least three of the following were present: waist circumference ≥ 102 cm in men and ≥ 88 cm in women; triglycerides ≥ 150 mg/dl (1.7 mmol/l); HDL cholesterol ≤ 40 mg/dl (1.0 mmol/l) in men and ≤ 50 mg/dl (1.3 mmol/l) in women; blood pressure $\geq 130/$

Table 1. Participating centres and patient populations (N, %) in the pilot and main studies.

Centre	Pilot study		Main study	
"C.C. Iliescu" Institute of Cardiovascular Disease, Bucharest	128	9.7	139	11.8
Covasna Cardiology Hospital (8 Departments)	573	43.2	436	37.1
Vrancea County Hospital, Focsani	32	2.4	42	3.6
Dambovit County Hospital, Targoviste	50	3.8	38	3.2
Galati Emergency University Hospital, Galati	84	6.3	76	6.5
Bacau Emergency County Hospital, Bacau	72	5.4	68	5.8
Ialomita Emergency County Hospital, Slobozia	28	2.1	27	2.3
Bihor University Hospital, Oradea	71	5.4	0	0
Valcea County Hospital, Ramnicu Valcea	83	6.3	75	6.4
Prahova Emergency County Hospital, Ploiesti	134	10.1	100	8.5
Arges County Hospital, Pitesti	45	3.4	18	1.5
Siret City Hospital, Suceava	26	2.0	0	0
Covasna County Hospital, Sf. Gheorghe	0	0	24	2.0
Ilfov County Hospital, Bucharest	0	0	37	3.1
"Prof. Dr. Agrippa Ionescu" Emergency Hospital, Bucharest	0	0	26	2.2
"Washington" CMDTA, Bucharest	0	0	4	0.3
"Prof. Dr. D. Gerota" Hospital, Bucharest	0	0	66	5.6

≥ 85 mmHg; fasting glucose ≥ 110 mg/dl (6.1 mmol/l). Using the IDF criteria,² the metabolic syndrome was diagnosed in patients with waist circumference ≥ 94 cm in men and ≥ 80 cm in women, plus at least two of the following conditions: triglycerides ≥ 150 mg/dl (1.7 mmol/l) or specific treatment for this lipid abnormality; HDL cholesterol ≤ 40 mg/dl (1.0 mmol/l) in men and ≤ 50 mg/dl (1.3 mmol/l) in women or specific treatment for this lipid abnormality; systolic blood pressure ≥ 130 mmHg or diastolic blood pressure ≥ 85 mmHg or treatment of previously diagnosed hypertension; and fasting plasma glucose ≥ 100 mg/dl (5.6 mmol/l) or previously diagnosed type 2 diabetes.

Written informed consent was obtained from all patients before data collection. The study was approved by the ethics committee of the participating centres.

Data collection

In the pilot study the participating physicians filled in a simple, anonymous, questionnaire with data regarding sex, weight, height, waist circumference and main reason for hospitalisation (coded diseases) for all patients hospitalised in their service on the study day. Presence or absence of MetS was defined according to NCEP ATP-III and was decided by investigators considering the local available data (blood sample results). Tables with raw data were forwarded to the cardiology department of the “Prof. Dr. C.C. Iliescu” Institute of Cardiovascular Diseases, Bucharest. For the main study, the questionnaire was modified and each diagnostic criterion of MetS was noted, as well as the presence, absence or history of angina, acute coronary syndromes, myocardial infarction, stroke, heart failure, or valvular heart diseases. Non-specific biological markers of inflammation (such as fibrinogen, leukocyte count, erythrocyte sedimentation rate), as well as markers of platelet activation (mean platelet volume, platelet distribution width) were added if available. All data collected were included in two databases, one for each study.

Statistical analysis

The data analysis was performed using EpiInfo 6.0 and EpiInfo 2005 statistical software (Centre for Disease Control, Atlanta, 2005). Population characteristics were reported as mean \pm standard deviation. Prevalence of MetS and abdominal obesity were calculated for unadjusted age and sex. Variables in the

subgroups with and without MetS were compared using the t-test. A p-value < 0.05 was considered statistically significant.

The agreement between the definitions of MetS was determined by the kappa statistic (κ).¹³ The level of agreement is considered “slight” with $\kappa < 0.20$, “fair” with $\kappa = 0.21$ to 0.40, “moderate” with $\kappa = 0.41$ to 0.60, “substantial” with $\kappa = 0.61$ to 0.80, and “nearly perfect” with $\kappa > 0.80$.

Results

The distribution of patients with respect to the observational centres is shown in Table 1. Note the large number of patients selected from Covasna Cardiology Hospital (second row), a hospital with a special regimen, where patients referred from all over the country are admitted for cardiovascular rehabilitation programs (including physical training, spa, etc.).

The clinical characteristics of the participants are given in Tables 2 and 3. Significant differences between men and women were noted regarding waist circumference (101.4 ± 13.7 vs. 94.7 ± 14.3 cm in the pilot study and 101.9 ± 13.3 vs. 98.2 ± 15.0 cm in the main study). The prevalence of pre-specified coded diseases in the study population for the main study is represented in Table 4. The only statistically significant difference was in valvular heart diseases, which were found more frequently in women compared to men.

The prevalence of MetS in the pilot study, using only NCEP ATP-III criteria, was 42.8% (45.9% in men and 39.4% in women, $p < 0.01$). In the main study, we noted a difference in the prevalence of MetS depending on the definition criteria used. Using NCEP ATP-III criteria, we calculated a MetS prevalence of 40.6% in the general population (38.3% in men and 42.3% in women). When the IDF criteria were used instead, the figures for the prevalence of metabolic syndrome were higher (44.2% in the general population, 43.1% in men and 45.3% in women). In the main study, the concordance between the two sets of criteria for the diagnosis of MetS (NCEP and IDF) was calculated as Cohen’s κ coefficient for inter-observer agreement¹³ and the values obtained, as well as values for P observed and P expected, are presented in Table 5. These values show a nearly perfect agreement ($\kappa > 0.80$) between the two diagnostic criteria for the general population and women; a substantial agreement was also observed for men.

Table 2. Clinical characteristics of patients in the pilot study.

Variables	All (n=1326)	Men (n=708)	Women (n=618)	p
Mean \pm SD				
Body mass index (kg/m ²)	28.2 \pm 5.0	28.4 \pm 4.7	28.1 \pm 5.4	<0.001
Waist circumference (cm)	98.3 \pm 14.4	101.4 \pm 13.7	94.7 \pm 14.3	<0.001
Number (%)				
Abdominal obesity – NCEP criteria	60.1	51.8	69.6	<0.001
Abdominal obesity – IDF criteria	79.6	74.3	85.8	<0.05
MetS prevalence	42.8	45.9	39.3	<0.01
Main reason for hospitalisation* (%)				
Acute coronary syndrome	12.9	13.3	12.5	NS
Ischaemic heart disease (other than ACS)	37.5	39.3	35.4	NS
Valvular heart disease	6.3	5.5	7.1	NS
Cardiomyopathy	3.5	4.8	2.1	<0.01
Congenital heart disease	0.8	0.3	1.5	<0.01
Other (including hypertension)	39.0	36.9	41.4	<0.05

*Only the main reason for hospital admission was recorded.

ACS – acute coronary syndromes; IDF – International Diabetes Federation; MetS – metabolic syndrome; NCEP – National Cholesterol Education Program Adult Treatment Panel III; SD – standard deviation.

Table 3. Clinical characteristics of patients in the main study.

Variables	All (n=1176)	Men (n=584)	Women (n=592)	p
Mean \pm SD				
Age (years)	61.4 \pm 11.1	61.3 \pm 11.4	61.6 \pm 10.8	NS
Body mass index (kg/m ²)	27.9 \pm 5.0	27.7 \pm 4.4	28.2 \pm 5.5	0.07
Waist circumference (cm)	100.0 \pm 14.3	101.9 \pm 13.3	98.2 \pm 15.0	<0.001
Triglycerides (mmol/l)	1.83 \pm 1.1	1.89 \pm 1.2	1.78 \pm 1.1	0.08
HDL-cholesterol (mmol/l)	1.21 \pm 0.3	1.14 \pm 0.3	1.28 \pm 0.3	<0.001
Fasting blood glucose (mmol/l)	5.84 \pm 1.8	5.91 \pm 1.9	5.78 \pm 1.7	NS
Leukocyte count ($\times 10^3/\mu\text{l}$)	7.46 \pm 2.6	7.67 \pm 2.3	7.25 \pm 2.9	<0.01
Fibrinogen (mg/dl)	404 \pm 123.7	400 \pm 127.3	408 \pm 120.0	NS
MPV (fL)	18.0 \pm 6.4	17.8 \pm 6.2	18.2 \pm 6.6	NS
PDW (fL)	8.76 \pm 1.7	8.70 \pm 1.7	8.83 \pm 1.8	NS
Number (%)				
Abdominal obesity (NCEP criteria)	63.7	51.4	75.8	<0.001
Abdominal obesity (IDF criteria)	80.5	74.5	86.5	<0.001
MetS prevalence (NCEP criteria)	40.6	38.3	42.8	0.06
MetS prevalence (IDF criteria)	44.2	43.2	45.1	NS
Diabetes	20.8	21.7	20.0	<0.05
Hypertension	67.2	65.0	69.2	0.06
Heart failure	29.5	17.6	31.4	0.07
Valvular heart disease	11.5	9.8	13.2	<0.05
Previous MI	13.4	27.6	9.3	<0.001
Previous stroke	6.5	7.2	5.7	NS

HDL – high density lipoproteins; MPV – mean platelet volume; PDW – platelet distribution width; MI – myocardial infarction. Other abbreviations as in Table 2.

The prevalence of abdominal obesity observed in the main study was 51.5% in men and 77.8% in women according to the NCEP ATP-III criteria, and 74.7% and 91.2% according to the IDF definition. It is worth noting the striking increase in the prevalence of abdominal obesity (almost 50%) that results from decreasing the cut-off value by only 8 cm. The distribu-

tion of population according to waist circumference value is represented in Figure 1 (mean waist circumference was 101.9 \pm 13.3 cm in men and 98.2 \pm 15.0 cm in women, median 102 cm and 99 cm, respectively). We observed a high frequency of obesity in our patients, especially in women.

Body mass index was calculated as the ratio of

Table 4. Prevalence of pre-specified diseases (%).

Disease	All (n=1176)	Men (n=584)	Women (n=592)	p
Acute coronary syndrome	15.6	17.2	14.0	0.06
Ischaemic heart disease	47.9	47.3	48.5	NS
Valvular heart disease	11.5	9.8	13.2	<0.05
Cardiomyopathy	14.2	15.1	13.3	NS
Congenital heart disease	1.8	1.7	1.9	NS

Table 5. Cohen κ inter-observer agreement for the two metabolic syndrome definitions used in the main study.

	κ	P observed	P expected
All patients	0.88	0.94	0.51
Men	0.79	0.90	0.52
Women	0.94	0.97	0.51

weight to height squared. Data for men and women are shown in Figure 2. If we compare men and women according to body mass index, another important marker for obesity, we observe that “overweight” is more frequent in the male than in the female population, whereas “obesity” (especially extreme obesity) is more frequent in women than in men (Figure 2).

The main study data allowed the calculation of relative risk associated with MetS for some diseases (Table 6). We noted a significant direct association of MetS with stable angina (RR=1.35, 95% CI: 1.20-1.53, $p < 0.001$), but not with acute coronary syndromes. Heart failure, valvular heart diseases and adult congenital heart diseases were significantly inversely correlated with the presence of MetS.

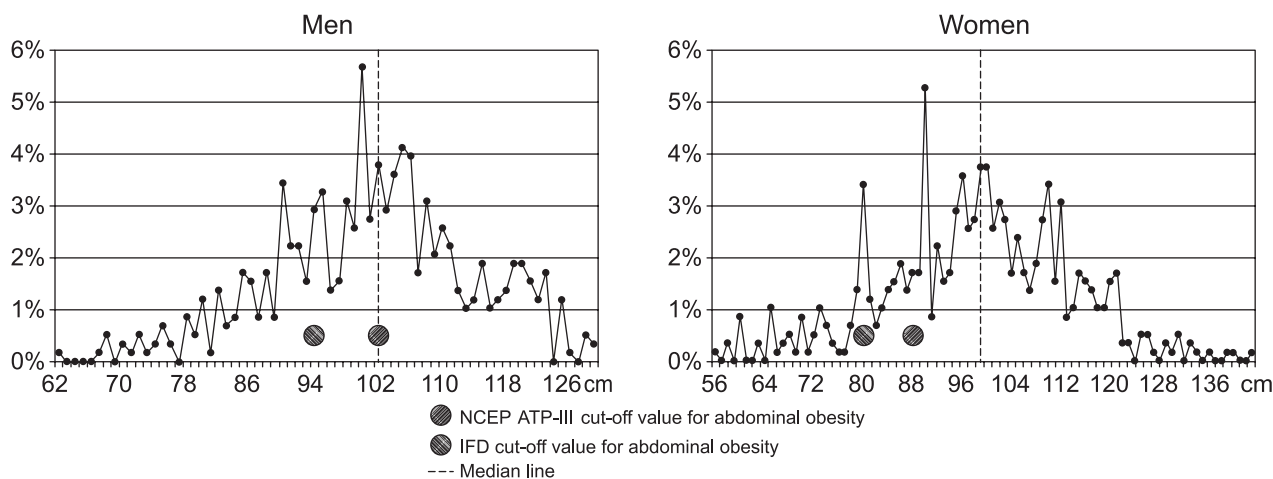


Figure 1. The distribution of population according to waist circumference. Cut-offs for abdominal obesity according to both definitions for metabolic syndrome are marked for each sex. The dotted line represents the median for study population. It is clear that obesity has a high prevalence, especially among the female population.

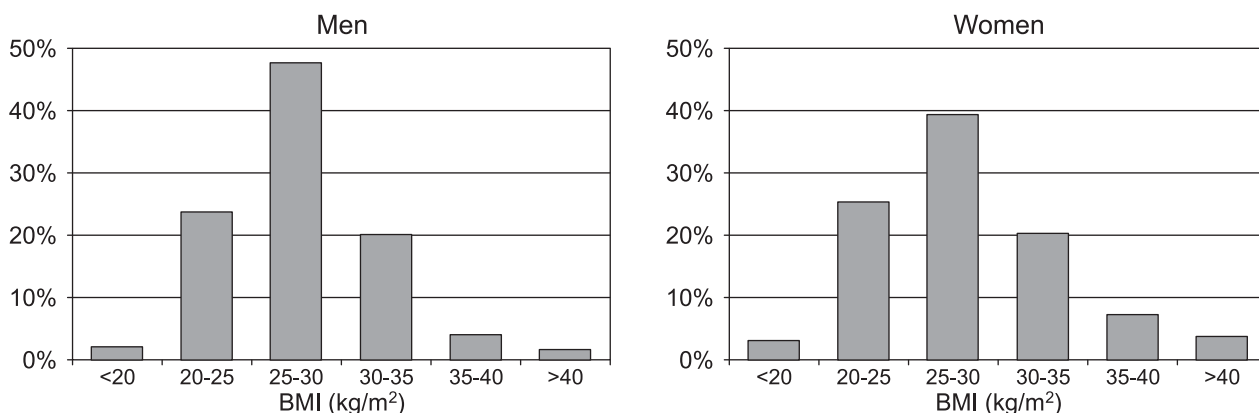


Figure 2. The distribution of population according to body mass index (BMI). It is important to note that overweight is highly prevalent in both men and women. This category and obese patients taken together represent more than half of the patients in the study.

Table 6. Relative risk associated with metabolic syndrome for various cardiovascular diseases.

Disease	NCEP ATP-III					IDF				
	MetS (n=478)	No MetS (n=698)	RR	95% CI	p	MetS (n=520)	No MetS (n=656)	RR	95% CI	p
Acute coronary syndrome	84	99	1.04	0.99-1.10	0.11	87	96	1.03	0.98-1.08	0.3
Stable angina	272	291	1.35	1.20-1.53	<0.001	296	267	1.38	1.22-1.55	<0.001
Previous MI	68	90	1.02	0.97-1.06	0.51	77	81	1.03	0.98-1.08	0.22
Cardiomyopathy	63	104	0.98	0.94-1.03	0.40	72	95	0.99	0.95-1.04	0.75
Valvular heart disease	42	93	0.95	0.91-0.99	0.01	52	83	0.97	0.93-1.01	0.15
Heart failure	119	228	0.90	0.83-0.96	<0.005	132	215	0.90	0.84-0.97	<0.01
Congenital heart disease	3	18	0.98	0.97-0.99	<0.01	4	17	0.98	0.97-1.00	0.02
Stroke	39	37	1.03	1.00-1.06	0.06	40	36	1.02	0.99-1.06	0.12

RR – relative risk; CI – confidence interval; MI – myocardial infarction. Other abbreviations as in Table 2.

Discussion

To the best of our knowledge, this is the first study of the prevalence of MetS that has been performed in Romania to date. The present study was designed to provide an overview of MetS in patients who were hospitalised in cardiology departments. Despite the limitation of this population selection (in-hospital), we believe our data are useful first of all as a sign of the increased prevalence of MetS in our country, as in all developed countries. Data from other studies^{10,14,15} have clearly shown that presence of MetS, increased waist circumference or body mass index, are strong predictors for future fatal and non-fatal cardiovascular events. For this reason it is of the utmost importance to have data about the prevalence of MetS, to inform decision makers so that they may devise strategies to decrease these figures.

Moreover, considering the risk associated with MetS, it is important to estimate the probability that an individual will develop cardiovascular or cerebrovascular disease in the future. Score-risk charts (such as Framingham charts or SCORE) are very useful, but variables like genetic heritage, social status, ethnic or cultural habits of a selected population are not taken into account.^{16,17} Calibration of international charts to a specific country could allow for these variables, enabling a more accurate estimation of risk. Our data could serve as a first step towards starting such a calibration for Romania. Similar figures for a high prevalence of MetS in specific subgroups with cardiovascular diseases were reported by the SMART study group in a selected population (i.e. hospitalised patients) in the Netherlands.⁷

Abdominal obesity is another point of concern. More than 50% patients in our study group were obese patients, a population with future high risk for major

cardiovascular and cerebrovascular events. As expected, the prevalence of abdominal obesity was higher if the IDF criteria were used. Moreover, abdominal obesity prevalence was higher in women than in men. This is an important problem of public health, reflected also in the special interest accorded to it, our data being compatible with data from US surveys (National Health and Nutrition Examination Survey).^{8,18} Educational programs and involvement of the mass media are important and useful tools for the continuous provision of information to the general population, since the root causes of the appearance and development of MetS are improper nutrition and inadequate physical activity. These habits, very difficult to change, are the keystones in our attempt to prevent the development of cardiovascular diseases.

Since the publication of the new IDF definition of MetS, there might be confusion among physicians as to which would be the best definition to use. We have shown in the present study that the agreement between the two definitions is substantial, with the IDF definition yielding a somewhat higher prevalence of MetS in the population. This can be easily explained by the lower threshold for both abdominal obesity and fasting glucose used by IDF. However, previous studies^{10,19} showed only a moderate-to-substantial agreement coefficient for these two definitions in various populations. One explanation could be that in our study population the prevalence of abdominal obesity was very high. Thus, the obligatory criterion imposed by the IDF definition is frequently also present in the NCEP ATP-III definition, with very good final agreement. It would be interesting to study the consistency of the two definitions further in a general population.

In this selected population of patients hospitalised in cardiology departments, MetS showed a significantly higher associated risk for stable coronary artery disease, but not for acute coronary syndromes. There was an inverse correlation between MetS presence and heart failure, valvular heart diseases and adult congenital heart disease. The consumptive nature of these conditions, often associated with a low body mass index, could explain this finding.

Conclusions

MetS represents a cluster of risk factors and is associated with an increased risk of cardiovascular morbidity and mortality. The prevalence of MetS is high and continuously increasing in the modern world. The new IDF definition further increases (somewhat artificially) the prevalence of MetS simply because of a slackening of the abdominal circumference criterion. Aggressive prevention and treatment are therefore needed in the management of MetS and its components in order to avoid an increase in the prevalence of cardiovascular diseases.

There are differences between European countries regarding the prevalence of risk factors and the incidence of cardiovascular diseases in the population; therefore, local epidemiological studies are important for national health strategies.

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