**Prevalence and control of cardiovascular risk factors in Romania cardio-zone national study***

*The study was performed with the contribution of Ozone Laboratories, Romania*

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**ABSTRACT**

**Background.** Cardiovascular disease (CVD) – including Coronary Artery Disease, Stroke, or Peripheral Arterial Disease – is the leading cause of mortality in Romania. Several risk factors (obesity – OB, smoking – SM, hypertension – HT, diabetes mellitus – DM, or hypercholesterolemia – Hchol) are associated with the development of CVD and their prevalence may vary by region of the country. However, there are few estimates of CVD risk factors burden or of its control status in Romania.

**Aims.** 1) to evaluate the prevalence of CVD and its risk factors in a general practitioners population among different regions in Romania and 2) to assess the status of control of CVD risk factors in this population.

**Design.** A cross-sectional study was conducted among an 8 EURO-regions in Romania (Bucharest, Muntenia, Oltenia, Banat, Crisana, Transilvania, Moldova and Dobrogea) between April and June 2006. From 17,330 questionnaires, 3,124 eligible individuals aged between 18 – 85 year old, 61 % female, were randomly selected to create a representative sample to respect age, gender and regional population distribution.

**Methods.** The following were standardly assessed: weight and height for calculation of body mass index, smoking status, arterial pressure, blood sample for measuring basal glucose and total cholesterol, history of angina and medical history questionnaire.

**Results.** The global prevalence of major CV risk factors (95% CI) was: HT – 39.1%, known DM – 11.8%, Hchol 31.4%, and SM – 21.7%. The general prevalence of the obesity was 26.3%, while the presence of other risk factors significantly increased the prevalence of OB (43% in diabetics vs 24% in non-diabetics, p<0.05). There was not significant difference of the CV risk factors prevalence among the EURO-regions, except Banat, where the prevalence of OB and HT was higher (38.3%, respectively 42.7%) and Muntenia, where the prevalence of diabetes was higher (22.6%). The presence of history of angina and stroke was significantly increased in diabetics when compared with non-diabetics (34.2% vs 11.5%, p<0.05 and 9.3% vs 2.5%, p<0.05). Despite the treatment, adequate control of blood pressure, blood glucose or total cholesterol was present in only 22.3% of patients with HT, 19.6% of patients with DM, and 39% of those with Hchol.

**Conclusions.** 1. General prevalence of CVD and its risk factors in Romania is high and there are no important differences in risk factors among the 8 EURO-regions. 2. Effective risk factors control among the general practitioners population is still poor.

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PREVALENCE AND CONTROL OF CARDIOVASCULAR RISK FACTORS IN ROMANIA CARDIO-ZONE NATIONAL STUDY

1. INTRODUCTION

Cardiovascular diseases (CVD), including coronary artery disease (CAD), stroke and peripheral arterial disease (PAD) represent one of the major public health issue, accounting for approximately one-fourth of all-cause mortality in the year 2000 (1,2). In recent years, CVD prevalence has slightly declined in the western societies; meanwhile over 80% of the global burden of CVD occurs in developing countries, where CV mortality is 2-to-5 fold higher than infectious disease mortality (3). Therefore, Eastern-European countries have persisting upward trend in CV mortality (4) and data of European Registry of Cardiovascular Disease show that Romania had one of the highest CV mortality of European countries, exceeding 8/1000 of citizens (5).

Beginning with the Framingham study, in 1961, it has been demonstrated that hypertension (HT), obesity (OB), smoking (SM), diabetes mellitus (DM), or hypercholesterolemia (Hchol) represent major risk factors for the development of CVD (6,7). The prevalence of CV risk factors may vary significantly among different populations, according to several factors, such as dietary and physical activity patterns, aging of the general population or the proper use of therapy for modify CV burden. Despite significant development of various therapeutical tools available to combat CV risk factors, the prevalence of these factors has remained unchanged and in some cases has even increased.

For the Eastern-European countries direct data on the prevalence of cardiovascular risk factors are lacking. Only few studies, such as WHO MONICA or REACH have included patients from Eastern Europe and their results showed that Eastern-European countries have a higher prevalence of CV risk factors and a lower effective control of them than the rest of Europe (8,9). However, there are even fewer estimates of CV risk factors burden, or of its control status in Romania.

CARDIO-Zone study is a national observational registry designed to estimate CVD and CV risk factor prevalence in the general practitioners population among an eight different EURO-regions in Romania and to assess the status of control of CV risk factors in this population. Furthermore, the present study compares the prevalence and control of the CV risk factors with the baseline data from the already existing epidemiological studies regarding Romanian population (SEPHAR – “Prevalence of the arterial hypertension and assessment of cardiovascular risk in Romania” and ATP – “Angina Treatment Pattern”).

2. MATERIALS AND METHODS

A cross-sectional study was conducted among a general practitioners population of an 8 EURO-regions in Romania (Bucharest, Muntenia, Oltenia, Banat, Crisana, Transilvania, Moldova and Dobrogea). Data were collected between April and June 2006. From 17,330 collected questionnaires, 3,124 eligible individuals aged between 18-85 year old, 61% female, were randomly selected to create a representative sample to respect age, gender and regional population distribution.

2.1. Data collecting

All participants were interviewed by a general practitioner, using a specific questionnaire, where the following variables were determined: gender, age, urban/rural inhabitant, schooling,
smoking status, past medical history and current diseases (diabetes mellitus, hypertension, angina pectoris, myocardial infarction, coronary revascularization, stroke, peripheral artery disease) and current medical treatment (antihypertensive, hypocholesterolemic, antidiabetic, antiplatelet agents).

Current smoking was defined as at least 5 cigarettes per day on average within last one month before entry into the CARDIO-Zone study; and former smoking as at least 5 cigarettes per day for more than three months before entry into the study; and all other were classified as non-smokers.

At this time, arterial pressure was measured three times using a standardized sphygmomanometer. According to the ESH/ESC criteria, subjects with systolic blood pressure (SBP) > 140 mm Hg and/or diastolic blood pressure (DBP) > 90 mm Hg, as well as those with previous history of hypertension and taking current antihypertensive medication for control blood pressure, were considered hypertensives.

Weight and height were measured in order to calculate body mass index (BMI), using the formula: weight (in kilograms) divided by the square of height (in meters). Subjects with BMI 25-29 were considered overweight and subjects with a BMI of ≥ 30 were considered obese.

Blood samples for total cholesterol and fasting glucose were collected. Subjects on lipid-lowering medication or those with total cholesterol > 200 mg/dl were considered hypercholesterolems. Individuals with fasting glucose = 126 mg/dl were considered hyperglycemics and those with history of diabetes mellitus and using oral glucose – lowering medication were considered diabetics. Documented CAD consisted of one or more of the following: history of stable angina, previous myocardial infarction, history of coronary angioplasty or stenting or coronary artery bypass grafting. Documented stroke consisted of a neurologist report with diagnosis of stroke. Documented PAD consisted of history of intermittent claudication or a previous intervention, such as angioplasty, bypass graft or even amputation.

The general practitioners were trained to complete the questionnaires and to perform blood measurements for cholesterol and glucose. This study was approved by the Ethics Committee in accordance with the Declaration of Helsinki. Informed consents were obtained from all participants at the study.

2.2. Data analysis

We collected 17,330 questionnaires from GPs that recruited subjects. We calculated that a sample size of 2,945 questionnaires were needed to detect diabetes and high blood pressure prevalence’s of 12.3% and 37.7% with a 2 and 3% precision at a 95% confidence and 80% power. Considering a missing data rate of 39% as assessed on a 122 subjects pilot analysis, 3,124 questionnaires were randomly selected using block randomization with blocks of 100, and analyzed.

For detecting a difference of 3mg/dl for glycemia among groups, with average of 96.7 mg/dl, and SD of 31.69, with 80% power, a 877 sample was needed, much less then the included number of 3,124.

Statistical analysis was performed using the SPSS version 13 for Mac OS X (Statistical Package for Social Sciences, 1989-2006). A descriptive analysis was made, and study variables were checked for normal distribution. We used two sample two tails t test (pooled variances) for normal distributed variables, and CI 95% estimation, c2 test or Fisher exact for values less then 5, c2 for proportions, Pearson r and Spearman rho for correlations, and c2 and McFadden Rho for statistical significance in logistic regression model.

3. RESULTS

3.1. Population

The 3,124 subjects (61% women, mean age 51±15 years) included in our study were equally distributed in the 8 geographic regions, as seen in Figure 1. 22.1% of the total population lived in rural areas, a proportion that
was fairly constant among 7 geographical regions with the exception of Muntenia where 58.8% of the subjects were included from rural area. Gender distribution was constant among regions and among age groups.

3.2. Cardiovascular risk factors

3.2.1. Smoking

A history of current or former smoker in the last 3 years was found in 19.9% of the subjects. From those, 72.5% were current smokers, which represented 21.7% of the total population. The incidence of non-smokers was constant among the regions, ranging between 66% and 75.1%, as shown in Figure 2. The incidence of smoking correlated with younger age: 39.4% of patients aged under 40 had a history of current or past smoking in the last 3 years, compared with 33.6% of patients aged between 40 and 55 years, 22.8% of patients aged between 55 and 70 years and 14% of patients aged over 75 years (p < 0.05 for all comparisons).

3.2.2. Diabetes

Hyperglycemia was present in 18.6% of the patients. Higher prevalence was reported for Muntenia and Bucharest (34.5% and 23.3%, respectively; p < 0.05 compared with the mean value for Romania). Hyperglycemia was also more common in the rural area compared with urban area (23.2% vs. 17.4%, p < 0.05). The prevalence of hyperglycemia also increased with age (p < 0.05 for all comparisons). Patients with a history of hypertension were also more prone to have hyperglycemia than patients without hypertension (19.8% vs. 10.3%, p < 0.05).

A history of known diabetes was present in 11.8% of the subjects. Again, Muntenia and Bucharest had higher percentages of subjects with known diabetes than the other 6 regions (22.6% and 17.6%, respectively; p < 0.05 compared with the mean for Romania), as seen in Figure 3. Among patients with diabetes, 73.8% received hypoglycemic treatment (either oral antidiabetics or insulin). However, the control of glycemia in diabetic subjects was poor: 76.7% had hyperglycemia. Diabetic patients on hypoglycemic medication had even poorer control than patients without medication (80.4% vs. 64.1% had hyperglycemia, p < 0.05) presumably because they had more severe diabetes.

The prevalence of diabetes also increased with age, from 1.6% in patients under 40 years of age, to 9.9% in patients aged between 40 and 55 years, 20.8% in patients aged between 55 and 70 years of age, and 19.9% in patients aged over 70 years (p < 0.05 for all comparisons).
The prevalence of obesity was higher in diabetic subjects than in nondiabetics (43.1% vs. 24.2%, p < 0.05). Hypertension was also more common in diabetic subjects than in nondiabetics (70.9% vs. 39.8%, p < 0.05).

### 3.2.3. Hypertension

A history of hypertension was found in 39.1% of the subjects. However, large differences between the 8 regions were found (Figure 4). As a group, 90.6% of hypertensive subjects received treatment. However, only 22.3% had normal blood pressure at the inclusion visit. The prevalence of hypertension increased with age, from 4.5% in patients aged under 40 years, to 34% in patients aged between 40 and 55 years, 63.9% in patients aged between 55 and 70 years, and 77.9% in patients aged over 70 years.
The severity of hypertension also increased with age (p < 0.05 for all comparisons).

3.2.4. Hypercholesterolemia

From the total population 31.4% had hypercholesterolemia. This percentage was similar in rural and urban areas. Among geographical regions the percentage of hypercholesterolemia was fairly similar in 6 of the regions (ranging between 23.8% and 32.6%) with the exception of Muntenia and Bucharest were the percentage of hypercholesterolemia was higher (38.3% and 46.1%, respectively; p < 0.05 compared with the mean for Romania). Hypercholesterolemia also increased with age (p < 0.05 for all comparisons). Patients who had hypertension or diabetes also had higher incidence of hypercholesterolemia compared with patients without a history of hypertension or diabetes (46.1% vs. 21.6%, and 52.9% vs. 28.7%, respectively; p < 0.05 for all comparisons), as seen in Figure 5. Among subjects with

FIGURE 5. Cholesterol level measurement and HT history

FIGURE 6. Obesity prevalence distribution on EURO-regions
hypercholesterolemia, only 32.9% received specific treatment.

3.2.5. Obesity

Of the total population, 26.3% was obese. Distribution of obesity was fairly similar between regions (ranging between 26.7% and 23.1%) with the exception of Banat, where it was 38.2%. Obesity was rare in patients aged under 40 years (11.9%).

3.3. Cardiovascular Diseases

3.3.1. Stable angina pectoris

The prevalence of angina pectoris was 14.2%. The lowest reported prevalence was in Moldova (7.2%) and the highest in Banat (23%), as showed in Figure 7. The prevalence was similar in rural and urban areas. As expected, the prevalence of angina increased with age (p < 0.05 for all comparisons).

3.3.2. Myocardial Infarction

A history of myocardial infarction was found in 2.4% of the subjects. The differences in prevalence among regions superimposed those of stable angina. The prevalence of myocardial infarction increased with age from 0.4% in subjects aged under 40 years, to 3.7% in subjects aged between 40 and 55 years, 3.9% in subjects aged between 55 and 70 years, and 6% in subjects aged over 70 years (p < 0.05 for all comparisons). Diabetic patients had a higher prevalence of myocardial infarction compared with subjects without diabetes (6% vs. 1.8%; p < 0.05) (Figure 8).

![FIGURE 7. Prevalence of stable angina history on EURO-regions](image)

![FIGURE 8. History of MI in diabetics vs non-diabetics](image)
3.3.3. Coronary revascularization

A history of coronary revascularization (either interventional or surgical) was present in 0.6% of the subjects. That corresponded to a history of coronary revascularization of 3.6% of the patients with a history of stable angina or myocardial infarction.

3.3.4. Peripheral Artery Disease

A history of peripheral artery disease was present in 3.6% of the subjects. The prevalence of peripheral artery disease increased with age from 0.3% in subjects aged under 40 years, to 2.3% in subjects aged between 40 and 55 years, 6.6% in subjects aged between 55 and 70 years, and 8.2% in subjects aged over 70 years (p < 0.05 for all comparisons).

3.3.5. Stroke

The prevalence of stroke was 3.3%, and it was identical in rural and urban areas. As expected, the prevalence of stroke increased with age from 0.1% in subjects aged under 40 years, to 1.8% in subjects aged between 40 and 55 years, 4.3% in subjects aged between 55 and 70 years, and 13.9% in subjects aged over 70 years (p < 0.05 for all comparisons).

3.3.6. Antiplatelet drugs

The prevalence of the use of antiplatelet drugs was 14% for the general population included in the study. The rate of antiplatelet drugs use was variable depending on the prevalence of the cardiovascular risk factors and cardiovascular disease. Thus, 35.2% of diabetics used antiplatelet drugs compared with 11% in non-diabetics (p < 0.05). Seventy-five percent of subjects with a history of myocardial infarction, 54.6% of subjects with a history of stable angina, 67.5% of subjects with a history of peripheral vascular disease, and 83.3% of subjects with a history of coronary revascularization used antiplatelet drugs.

4. DISCUSSIONS

Regarding the fact that CVD represent the leading cause of death in Romania (10), the knowledge of prevalence of the CV risk factors in different regions of Romania is of a major importance in order to create national health strategies for their controls. The global results of our study showed that the prevalence of CV risk factors in Romania is high, with minimal difference in their distribution among the EURO-regions, except Banat, where the prevalence of obesity and hypertension was higher (38.3% and 42.7% respectively), and Muntenia, where the prevalence of diabetes was higher (22.6%). Furthermore, the data of our study showed that there was a high proportion of treated subjects not achieving therapeutical targets for hypertension, diabetes or hypercholesterolemia. This results partially explained the high mortality rates for CVD in Romania.

The CARDIO-Zone study is a global study that estimate the prevalence of CV risk factors and of CVD, and also the control rate of these different regions of Romania. The number of included subjects, the sample size and method of selection ensure the external validity of this study, and thus, the obtained results may be extrapolated to the entire Romanian population.

This study was one of the first major epidemiological studies undergone to assess the prevalence of major CV risk factors and cardiovascular disease in 8 Romanian regions. In the moment when our study began (spring 2006) similar data for Romania were only available from the reported data for the World Health Organization by the Romanian Health Ministry. However, this data were primarily gathered from hospital statistics, and thus represented selected data.

Since than two important studies dealing with this subject were published: the SEPHAR study (2006) and the ATP study (2008) (11,12). These studies were performed completely independent from our study. A comparison of the different results in these studies in respect with CARDIO-Zone is presented in Table 1.

As we know, smoking is a major risk factor for atherothrombotic events, accounting an 80% increased risk of CAD for smokers and a 30% increased risk for passive smokers (13). Furthermore, smokers of all ages have a two-three times higher death rates than non-smokers (14). In the CARDIO-Zone population, the prevalence of current smoking was 21.7%, a characteristic of area with predominantly urban and under 40 years population. In the SEPHAR population, there was also an high prevalence of current smokers (29 %), but in contrast with the findings of ATP study, where the prevalence was only 9%. This difference may be attributed

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to the fact that most of the ATP patients stopped smoking, since that they have declared CAD. If we consider former plus current smoker, the combined figure is greater than in our study, which is also normal, the population in ATP being a selected CAD population.

Hypertension is also a major risk factor for atherosclerotic events, with an event attributable risk of 30 % (15). Data of WHO estimate that high blood pressure is responsible for over a 50 % of CAD and over a 75 % of stroke (1). Hypertension prevalence was found variable in

### TABLE 1. A comprehensive comparison between the CARDIO-Zone study, SEPHAR study and ATP study regarding prevalence of CV risk factors in Romania.

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>CARDIO-Zone (%)</th>
<th>SEPHAR (%)</th>
<th>ATP (%)</th>
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<tbody>
<tr>
<td><strong>Smoking</strong></td>
<td></td>
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<tr>
<td>^ smoker in the last 3 years, non smokers at present.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>†† known diabetes or/and on oral antidiabetics or/and on insulin</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>† fasting glycemia &gt;126mg/dl and/or history of diabetes and/or on antidiabetics</td>
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<td></td>
<td></td>
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<tr>
<td>* glucose level above normal measured in capillary blood, one determination</td>
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</tr>
<tr>
<td>** blood glucose &gt;100mg/dl and &lt;126 mg/dl.</td>
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Hypertension prevalence was found variable in
these three Romanian studies. According to the SEPHAR study, 17.2% of the Romanian adult population has a history of hypertension. The prevalence of hypertension history found in our study – 39% – is higher than in the SEPHAR study. The difference in urban-rural range among the populations compared, and probably the different dietary and physical activity habits may have contributed to the differences found. In ATP study the prevalence of hypertension was very high, of 80%. As said, ATP population is a selected CAD population, which explains the high prevalence of risk factors, but the presence of HT is however unusually high. Taken into account the three studies discussed here, a prevalence of HT of 30-35% is probably found in the adult population of Romania, that is higher than in SEPHAR and lower than in CARDIO-Zone. In CARDIO-Zone the population selected had some medical problems for which addressed to the family doctor, so it is not a completely random adult population. On the contrary, when developing CAD, like in ATP study population, hypertension proves to be a very strong risk factor, being present in 80% of cases.

Obesity prevalence is increasing all across the world and has become a general public health issue. Recent studies demonstrated that overweight and obesity increase the CAD risk by 1.40 to 1.65 fold in men and 1.32 to 1.83 fold in women (16). Furthermore, the multiple adjusted risk of ischemic and hemorrhagic stroke is increased by 4% and 6%, respectively, with each one-unit increase in BMI (17). Our study reported a high prevalence in obesity (26%). Similar results were reported also for the SEPHAR and ATP population (24% and 31%, respectively).

The National Cholesterol Education Program (NCEP) and most other consensus guidelines define diabetes as a CAD equivalent. This consideration derived from the fact that diabetic patients without previous myocardial infarction have an almost identical risk of CAD death with the nondiabetic patients with previous myocardial infarction (18). Literature data described a more frequent occurrence of other CV risk factors among patients with diabetes (19), data sustained also by our findings. Therefore, the presence of hypertension and obesity was significantly increased in diabetics when compared with non-diabetics (71% and 43%, respectively). Overall, the global prevalence of DM reported by our study was 11.8%, that is high comparing to the literature, where DM prevalence ranges from 4% to 12%. In a nationwide, SEPHAR study reported a DM prevalence of 5%. In the CAD population of ATP the prevalence was of 21%. The prevalence of DM found in our study, at the superior limit of the prevalence reported in the literature in similar adult population may be associated with the higher prevalence of HT and OB, since they often occur together. Also, dietary habits and level of physical activity may be implied and warrant further investigations.

Regarding the lipid levels, Hchol prevalence reported by our study was higher than that found in SEPHAR study (31.4% vs 24%) and lower than that found in ATP study (65%). The explanation could be the same as in the case of diabetes mellitus.

As we already mentioned, established CAD, including stable or unstable angina, previous MI or coronary revascularization represent most important causes of mortality and disability all over the world (1). Literature data showed that between 18-23% of men and women die within 1 year of having an initial MI, whereas 7% to 30% of patients develop symptomatic heart failure (20). The presence of at least one of the four important risk factors (HT, SM, Hchol, DM) is found in 80-90% of patients with asymptomatic CAD (21). The prevalence reported by our study for the stable angina, previous MI or coronary revascularization were: 14.2%, 2.3% and 0.6%, respectively. These figures of prevalence were lower than those published by the ATP study (65% of stable angina, 20% of previous MI and 10.4% of coronary revascularization), but define Romania as one of the highest prevalence CVD countries. These findings may be explained by the low use of antiplatelet drugs (13.9% of total population), by the high prevalence of major CV risk factors, and also by other specific psychosocial factors, reduced fruit and vegetable consumption, excessive alcohol intake and too little physical activity.

Only 3.6% of our study population was identified with PAD, probably attributed to a lack of ankle-brachial index measurement. This prevalence was lower than the 15% figure found in the ATP study, but similar with that found in general population, which was estimated at about 3.9% in males and 3.3% in females and considered close age-dependent (22). Also, our study reported a lower prevalence
of stroke (3.3 %) in comparison to that reported by the ATP study (14%).

Literature data showed that despite of several guidelines published by the international Health Care Organization for managing the high-risk patients, CV risk factors remain significantly undertreated across the world. Therefore, a recent registry – Reduction of Atherothrombosis for Continued Health (REACH) demonstrated that 40-70% of included patients have a blood pressure level = 140/90 mmHg (2). The regions with the lowest HT control were Eastern Europe, followed by Middle East, and Latin America. In addition, 20-70% of these patients continue to have elevated total cholesterol (> 200 mg/dl) despite the treatment (2). Our study results confirm these findings, showing that only 22.3% of patients taking medication for HT have normal blood pressure, 16.2% of patients taking hypolipemiant drugs have normal total cholesterol and, only 19.6% of patients receiving antidiabetics or insulin have an optimal glycemic control. Similar results have been reported also by the ATP study. Moreover, data from National Health and Nutrition Examination Survey (NHANES) 2001-2002 demonstrated that only 29% of patients with combined HT and Hchol received treatment (23). Our study results confirm these data, demonstrating that only 36.6% of hypertensive patients, 8.9% of diabetic patients, and 16.2% of hypercholesterolemic patients received medication.

Several limitations of our study should be considered. First, although we were measured the fasting blood glucose, oral glucose tolerance were not evaluated in our study, lacking therefore the estimation of pre-diabetes. Likewise, the cholesterol fractions were not measured. Second, the diagnosis of PAD and CAD were made based on clinical history, without performing of ankle-brachial index measurement or electrocardiogram, therefore the prevalence of PAD and CAD may be underestimated. Finally, data collection was done thought the general practitioner office and the selection bias was controled, however the population is still of patients.

In conclusion, the data from the CARDIO-Zone study showed that general prevalence of CVD and its risk factors in Romania is high and in general we did not find important differences in risk factors levels among the 8 EURO-regions. Some differences, such as the obesity prevalence, almost double in Banat as in Muntenia (38.5% versus 23.5%, respectively) do not change the overall appearance of homogeneity in bad. Moreover, this study showed that effective risk factors control among the general practitioners population is still poor. Therefore, public health strategies, including lifestyle interventions along with using of effective pharmacological therapy, should be implemented in order to reduce CV risk in Romanian population.

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