

The SEPHAR-FUp 2020 Project (Study for the Evaluation of Prevalence of Hypertension and Cardiovascular Risk in Romania – Follow-up 2020)

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Received: December 2, 2020, Accepted: February 2, 2021

Abstract

The Study for the Evaluation of Prevalence of Hypertension and Cardiovascular Risk in Romania (SEPHAR) project, which encompassed three epidemiological surveys, assessed the prevalence of hypertension and other cardiovascular risk factors in the adult population of Romania and provided an estimation of the trend in the prevalence of these factors. The need to confirm this estimated future trend led to a new epidemiologic survey – SEPHAR FOLLOW-UP. This paper aims to summarize the objectives and methodology of this survey. The study population is the same as in SEPHAR III, thus allowing to assess the prevalence of hypertensive patients’ compliance to treatment. The fieldwork will be performed by 10 investigators teams in 84 study sites, using a medically equipped caravan. All subjects will undergo two visits, four days apart, during which the teams will assess their anthropometric measurements, blood pressure, arterial rigidity, ankle-brachial index, 12-lead electrocardiogram (ECG), standard echocardiography, as well as a study questionnaire and blood and urine samples. The survey results might guide public health policies towards tailored preventive strategies to reduce the cardiovascular risk of the adult population in Romania.

Keywords: arterial hypertension, SEPHAR, target-organ damage, compliance.

Introduction

Cardiovascular diseases remain the most frequent cause of mortality in the western world [1]. There are great disparities regarding the cardiovascular mortality curve between Eastern Europe (where it

is constantly rising) and Western Europe (where it is constantly declining). In Romania, the burden of cardiovascular disease is mainly due to arterial hypertension (HT), which, together with its complications, determines 62% of total deaths [2]. Currently, since the genetic modulation of cardiovascular diseases still warrants further research, the most effective strategy is modifying the main cardiovascular risk factors. From a public health policy standpoint, knowing the evolution trend of the prevalence of risk factors is of utmost importance, allowing intervention upon the mortality curve by implementing strategies of cardiovascular prevention [3].

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The lack of representative data regarding the prevalence of cardiovascular risk factors in the entire Romanian population led to the “Study for the Evaluation of Prevalence of Hypertension and Cardiovascular Risk in Romania” (SEPHAR) project. In 2005, the first epidemiologic survey (SEPHAR I) was carried out. It confirmed that Romania is a country at a high total cardiovascular risk, with a high prevalence of both arterial HT (44.9%) and other risk factors [4–6]. The second epidemiologic survey, SEPHAR II, which was carried out in 2012, showed a descending trend in the prevalence of HT, as well as an ascending trend in the number of hypertensive patients receiving medication and in the number of hypertensive patients with optimal blood pressure (BP) control [7–9]. Despite these encouraging results, SEPHAR II also revealed an increasing trend in the prevalence of other cardiovascular risk factors, such as diabetes mellitus, obesity and dyslipidemia. SEPHAR III, which was carried out in 2016, assessed not only the prevalence of HT and BP control but also of HT-induced target-organ damage [10–11]. The three SEPHAR surveys allowed the evaluation of the trend in prevalence and control of HT and major cardiovascular risk factors while also providing an estimation of their future trend in the following five years.

In this context, the above-mentioned estimated tendency of the prevalence of HT and major cardiovascular risk factors needs to be confirmed in a follow-up survey. This paper aims to describe the objectives and methodology of SEPHAR FOLLOW-UP 2020. The survey is conducted by the “Life without hypertension” Foundation, which is coordinated by Professor Maria Dorobantu.

SEPHAR FOLLOW-UP 2020 objectives

1. Assessing the prevalence and incidence of HT and other major cardiovascular risk factors in the adult population in Romania in 2020;
2. Assessing the past trend in the prevalence of HT, as well as the awareness of HT in the adult population in Romania between 2016 and 2020;
3. Assessing the past trend in BP control in the adult population in Romania between 2016 and 2020;
4. Assessing the past trend in the prevalence of major cardiovascular risk factors in the adult population in Romania between 2016 and 2020;
5. Assessing the total cardiovascular risk in the adult population in Romania, based on the laboratory and imagistic tests performed;
6. Assessing the prevalence, awareness, treatment and control (according to the cardiovascular risk category) of dyslipidemia in the

adult population in Romania between 2016 and 2020, as well as the evolution trend for these parameters in the same period;

7. Assessing the prevalence of familial dyslipidemia in the adult population in Romania;
8. Assessing the salt consumption in the adult population in Romania and its evolution trend between 2016 and 2020, which could represent the basis for a law project regarding the decrease in dietary salt intake;
9. Estimating the prevalence of obstructive sleep apnea in the adult population in Romania;
10. Assessing the effects of the law that restricts smoking in public places upon the cardiovascular risk of the adult population in Romania.

Material and methods

Study population

The sample population of SEPHAR FOLLOW-UP 2020 consists of the 1970 subjects who were enrolled in SEPHAR III and who will provide informed consent for participation in this new survey. A subject not willing to participate in SEPHAR FOLLOW-UP 2020 may be replaced by a different age-, sex- and regional belonging-matched subject. A maximum of 591 new subjects is allowed to ensure a representative sample of at least 1379 subjects from the whole study population of 1970 subjects in SEPHAR III.

Regional territories and the SEPHAR FOLLOW-UP team

The total area of Romania was divided into 9 regions plus Bucharest, encompassing a total of 84 study sites where the survey will be carried out. Each of the 10 regions will have its own fieldwork team, which will consist of four members:

- 1 coordinating investigator (a cardiology specialist);
- 2 sub-investigators (two senior residents in cardiology);
- 1 nurse assigned by the central laboratory.

The fieldwork will be performed in a special medical caravan – SEPHAR BUS, fully equipped with medical and laboratory equipment required for the clinical, laboratory and echocardiographic assessments, which will travel to each of the study sites, according to the regional schedule of the survey.

Investigators and sub-investigators received specific training concerning the filling of the questionnaire and the correct anthropometric, BP and

arterial rigidity measurements, as well as proper echocardiographic image acquisitions. All the nurses received specific training regarding the collection and transportation of biological samples.

Similar to previous SEPHAR surveys, SEPHAR FOLLOW-UP includes two visits, 4 days apart (Figure 1). The study will last 3 months.

During the first visit, the investigator and sub-investigators will briefly explain the aims of the survey, and the subjects will provide written informed consent. Afterward, for each subject, the medical team will fill in the questionnaire, and they will perform anthropometric measurements, BP measurements, and a 12-lead electrocardiogram (ECG) while scheduling the second visit and instructing the subjects how to prepare for fasting blood sampling and how to collect a 24-hour urine sample. Subjects who own an arm sphygmomanometer will be instructed how to self-monitor their BP at home and fill in the results in a special brochure.

During the second visit, the investigator and sub-investigators will perform a new series of BP measurements, standard echocardiographic acquisitions, arterial rigidity, and ankle-brachial index (ABI) measurements, as well as collecting the brochures from the subjects who were able to self-monitor their BP at home. At the same time, the nurse will collect the blood and urine samples, which will be transported to the central laboratory in a maximum of two hours.

Data collection

Study questionnaire

The study questionnaire consists of 51 items:

- 11 items regarding socio-demographic data;
- 10 items regarding medical history and cardiovascular risk factors;

- 15 items regarding the awareness of cardiovascular prevention and complications due to poor control of risk factors, the source of knowledge; about health and disease as well as usage of preventive methods;
- 1 item regarding medication;
- 6 items regarding the Morisky Medication Adherence Scale;
- 8 items regarding the Epworth Sleepiness Scale.

Anthropometric measurements

The anthropometric measurements will be performed as follows:

- Weight will be measured using an electronic scale with a maximum deviation of 0.1 kg, with the subject wearing light clothes;
- Height will be assessed using a measuring device with a maximum deviation of 0.5 cm;
- Waist circumference, hip circumference, arm circumference, distance from the suprasternal notch to the pubic symphysis and neck circumference will be measured using a tailor’s measuring tool with a maximum deviation of 0.5 cm.

Blood pressure measurements

BP measurements will be performed using an automatic oscillometric BP measuring device certified by the Association for the Advancement of Medical Instrumentation (AAMI). The same devices will be used throughout the entire survey and throughout all the 8 geographic regions; the use of other devices is strictly forbidden. Measurements will be taken according to the current European Society of Hypertension (ESH) guidelines for BP measurement [12].

The subject’s arm circumference will be measured previous to BP measurements; in case of an arm circumference larger than 32 cm, a cuff for obese subjects will be used. BP will be measured

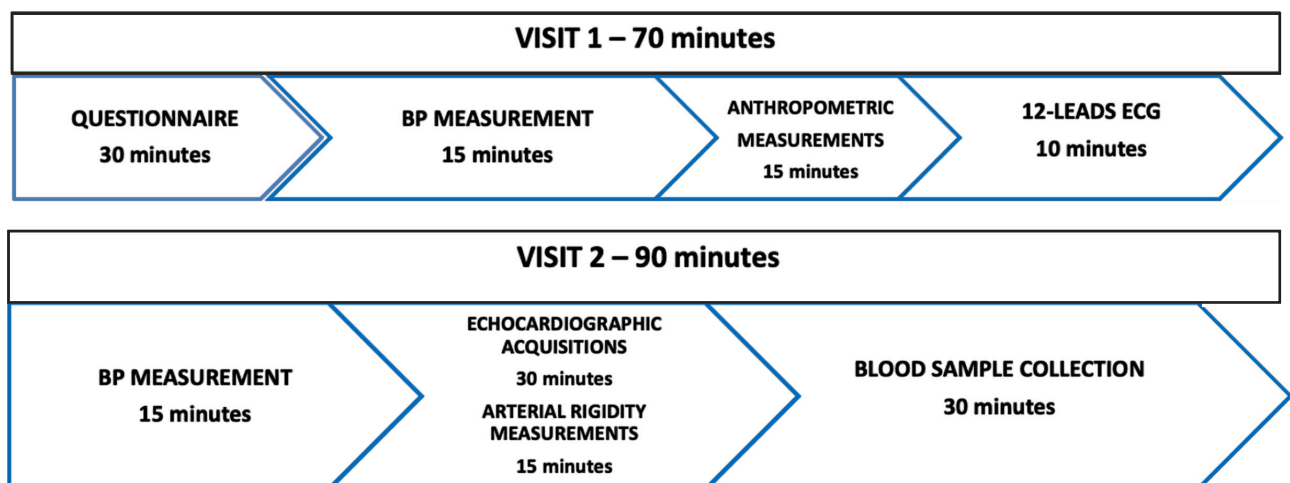


Figure 1. Visits’ flow chart with time estimates for each of the collected data. BP – blood pressure, ECG – electrocardiogram.

in both arms in order to select the arm with the highest BP value for further measurements. Three consecutive measurements of systolic and diastolic BP will be performed, one minute apart. Afterward, BP will be measured in orthostatism at one minute and three minutes, respectively, to check for orthostatic hypotension. The same BP measurements will be taken at the second visit as well.

12-lead ECG recordings

The 12-lead ECG recordings will be performed with standard electrode placement, with the patient in a supine position, standing still, and breathing normally. Another ECG will be recorded during post-inspiratory apnea in order to identify modifications due to a horizontal position of the heart.

Transthoracic echocardiography

Standard transthoracic echocardiography will be performed with the patients in the left lateral decubitus position, ECG-gated, with image acquisitions over 3 cardiac cycles. Two-dimensional, color Doppler and spectral Doppler acquisitions will be performed in parasternal long- and short-axis windows, as well as apical four-, two- three- and five-chamber windows in order to measure the following parameters: the thickness of the interventricular septum, thickness of the left ventricular (LV) posterior wall, LV mass, LV ejection fraction, trans-mitral E/A ratio, left atrial area, left atrial volume. Echocardiographic measurements will be afterward performed at a workstation by 2 independent researchers.

Arterial stiffness measurements

Arterial stiffness will be assessed using an oscillometer (Arteriograph TensioMed) with the subject at rest, in a supine position, on the dominant arm. The following parameters will be measured: aortic pulse wave velocity, aortic augmentation index, aortic systolic BP, aortic pulse pressure, reverse time, systolic area index, diastolic area index, ejection duration and diastolic reflection area.

Ankle-brachial index measurements

The ABI will be assessed using a Doppler pencil and an adequately sized BP cuff. For the BP in each leg, the investigators will choose the highest value between systolic BP in the posterior tibial artery and systolic BP in the dorsalis pedis artery. Both a right ABI and a left one will be calculated by dividing the BP in the respective leg to the highest between left brachial artery BP and right brachial artery BP. The ABI for each subject will be the smallest between right ABI and left ABI.

Blood and urine sample collection

Blood samples will be drawn by the nurse after checking the proper fasting time before the test (between 8 and 14 hours). The samples will be collect-

ed with the subject sitting. Afterward, the nurse will mark the test tubes with the subject's study code, will take the recipient with the collected urine, and will prepare the blood and urine samples for transportation. The laboratory tests that will be performed are total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, apolipoprotein B, blood glucose, glycated hemoglobin, serum creatinine, uric acid, albuminuria, urinary sodium, urinary creatinine, urine albumin-to-creatinine ratio.

Discussion

While similar to the three previous SEPHAR surveys in terms of collected data and other methodological aspects, the novelty of SEPHAR FOLLOW-UP is that the study population is the same as in SEPHAR III. First, this will allow the measurement of the incidence of hypertension among the adult population in Romania. Second, it will assess the accuracy of the previously estimated trend in the prevalence of HT and other cardiovascular risk factors (derived from the previous SEPHAR surveys). Third, it will allow the assessment of patients' compliance to antihypertensive treatment and the assessment of the evolution trend of optimal BP control in hypertensive patients. Last but not least, the survey will allow the assessment of the evolution trend of salt consumption among the adult population in Romania between 2016 and 2020.

Conclusion

SEPHAR FOLLOW-UP will provide important information regarding the trend in the prevalence of hypertension and other cardiovascular risk factors among the adult population in Romania, as well as information regarding the trend in hypertensive patients' compliance to treatment and the trend in optimal blood pressure control for these patients. Thus, the study may guide the implementation of specific preventive strategies in a country at high cardiovascular risk, ultimately aiming at reducing the global burden of cardiovascular disease.

Acknowledgment

The survey is completed thanks to financial support from SERVIER PHARMA, KRKA Romania, SANOFI Romania and TERAPIA.

Conflict of Interest

The author confirms that there are no conflicts of interest.

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