

Pharmacology and Pharmacogenomics

2022; 1(1): 101-106. doi: 10.31488/jpp.101

Protocol

Observational Study to Evaluate the Efficacy of an Intervention with a Low Sodium Diet using Urine Sodium Monitoring in Patients with Arterial Hypertension (AHT) in the Primary Care Setting

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Received: December 06, 2021; Accepted: January 05, 2022; Published: January 07, 2022

Abstract

Arterial hypertension (AHT) is an independent vascular risk factor and a frequent reason for consultation in primary care. It generates high cardiovascular morbidity and mortality (stroke, heart disease, renal failure and other diseases). Moreover, given that it is a modifiable factor and that there are intervention and control measures that would lead to a significant reduction in cardiovascular incidence and morbidity and mortality, it can be stated that AHT constitutes an important public health problem. The approach to this risk factor can be pharmacological or nonpharmacological. The nonpharmacological approach is based on lifestyle modifications. Among the measures aimed at modifying lifestyles is the restriction of daily dietary sodium intake. This restriction enhances the hypotensive effect of pharmacological treatment, so that its application and intensification would delay the initiation of pharmacological therapy, as well as avoid the need to increase the dose of antihypertensive drugs or the number of drugs used to control hypertension. With regard to salt intake in the Spanish population, the average is above the figures of less than 5 grams per day recommended by the WHO. Sodium intake can be estimated by determining the concentration of sodium in 24-hour urine. In addition, there is a positive correlation between systolic and diastolic blood pressure and urinary sodium excretion. In the present study, with a prospective cohort observational design, we intend to evaluate the efficacy of the use of an educational program based on the follow-up of a low sodium diet and assessed by the routine use of urinary sodium monitoring in hypertensive patients in the primary care setting, in order to optimize treatment, as well as to review the clinical control in this group of patients. On the other hand, the aim is to establish guidelines in the form of practical guides that would provide us with a standardized clinical approach for primary care centers.

Keywords: Low sodium diet, urine sodium, arterial hypertension, lifestyle, educational program

Introduction and Justification for the Study

Arterial hypertension (AHT) is an independent major cardiovascular risk factor with a prevalence of around 30-45%, being 24% and 20% in males and females, respectively [1,2]. Primary care, as the first level of health care, is responsible for the screening, diagnosis, treatment and follow-up of arterial hypertension. This cardiovascular risk factor is the cause of high cardiovascular morbidity and mortality: stroke, heart disease and renal failure.

Genetic and environmental factors are involved in the etiol-

ogy of AHT. The therapeutic approach to AHT is based, on the one hand, on antihypertensive drugs and, on the other hand, on lifestyle modifications (LM) [15]. Among the LM is the restriction of sodium intake. Epidemiological studies in the scientific literature show a linear relationship between sodium intake and blood pressure levels.

Among these studies is the worldwide INTERSALT16 study, which analyzed 1,079 patients between 20 and 59 years of age

from 32 countries. This study found a significant and positive linear relationship between 24-hour urinary sodium excretion and blood pressure (BP). Between 50-60% of hypertensive patients were “salt sensitive” [14], i.e., they presented elevations in blood pressure (BP) with salt intake, with a greater risk of target organ damage (left ventricular hypertrophy, microalbuminuria) and greater cardiovascular risk. In addition, urinary potassium excretion was analyzed in this study, and an inverse relationship between potassium and blood pressure was observed, i.e., low potassium excretion with high blood pressure with cardiovascular implications. In the experimental studies THOP I and THOP II (Trials of Hypertension Prevention, 2007), in which more than 2000 patients were analyzed in each study, the efficacy of sodium reduction in reducing BP was demonstrated and, in the long term, showed a 25% reduction in cardiovascular events [4,5].

Another study that has demonstrated the benefits of the low sodium diet is the multicenter sodium-DASH clinical trial where slightly more than 400 patients with and without hypertension subjected to diets with different levels of sodium and rich in fruits, vegetables and low-fat dairy products were analyzed. The benefit of dietary sodium reduction in reducing BP7 was again demonstrated.

A 2013 meta-analysis (Cochrane Database Syst Rev. Apr 30) [9,10] where 34 clinical trials (3230 patients) were analyzed objectified that reducing salt intake over four or more weeks significantly reduced blood pressure (with greater effect on systolic) and 24-hour urine sodium. Another 2017 meta-analysis (Cochrane Database Syst Rev. Apr 9) included 185 clinical trials again showing that the administration of a low sodium diet produced significant blood pressure reductions of up to 5 mmHg in systolic and up to 3 mmHg in diastolic blood pressure.

At the national level, a study published in the British Medical Journal of Nutrition (2011) [13], where 418 Spanish patients were evaluated, showed that the mean 24h urinary sodium was 168 mmol/d corresponding to a sodium intake of 4.6 g/d (9.8 g/d of salt) figures above those recommended by the WHO. The systolic and diastolic blood pressure figures correlated positively with urinary sodium excretion.

In the literature reviewed, no significant studies have been found at primary care level based on the evaluation of a low sodium diet intervention, reduction of blood pressure and urinary sodium monitoring. Hence the interest of this work.

High sodium intake (>2g /day, equivalent to 5 g of salt per day) present, among others, in processed foods plus added in home food preparation and insufficient potassium absorption (less than 3.5 g/day), due to lower consumption of fruits and vegetables, contribute to high blood pressure and increase the risk of developing cardiovascular disease. The WHO recommends a reduction in sodium intake of <2 g/day (equivalent to <5 g of salt/sodium chloride, slightly less than a teaspoon) and an increase in potassium intake to lower blood pressure.

To this end, he proposes several strategies, among which the following stand out at the local level: Providing specific dietary advice to people attending health centers. Reducing salt intake is considered a cost-effective measure that contributes to lowering blood pressure, cardiovascular risk, stroke and ischemic heart disease. It is the responsibility of primary care to promote this lifestyle modification.

This project will make it possible to evaluate the efficacy of the educational programs promoted by Primary Care related to a low sodium diet by monitoring sodium in urine and additionally potassium, together with a review of blood pressure figures and studies of the impact on quality of life. If such efficacy is demonstrated, this would make it possible to reduce the problems derived from hypertensive pathology, improve the effectiveness of antihypertensive drugs and reduce health care costs in the national health care system.

Objectives and Purpose of the Study

Hypothesis of the study

The implementation and reinforcement of an educational program (direct action on the patient and delivery of educational materials) on a healthy lifestyle habit in the Primary Care setting such as the reduction of sodium intake in hypertensive patients, will improve compliance with the hyposodic diet, which can be verified by monitoring sodium concentrations in urine, and will result in greater control of hypertension in these patients (improvement in blood pressure, lower consumption of antihypertensive drugs) and an improvement in their perceived quality of life.

Main objective

To evaluate the efficacy of the educational intervention related to the low sodium diet on the control of blood pressure in patients with poorly controlled hypertension in the primary care setting.

Secondary Objectives

- To analyze the usefulness of urine sodium monitoring for compliance and follow-up of the low sodium diet after educational intervention.
- To compare the concordance between sodium levels in 24h urine samples and urine samples from isolated micturition.
- To analyze the use of antihypertensive drugs after the educational intervention.
- To monitor urinary potassium levels as an additional method in the follow-up of diet and educational intervention.
- To study the impact of the educational intervention on the quality of life in patients with hypertension.
- To verify compliance with the hyposodic diet and pharmacological treatment by means of questionnaires.

Strategic objectives based on the results obtained

- To encourage the modification of lifestyles, with emphasis on the implementation of a hyposodic diet, as a basic measure in the management of hypertensive patients with poorly controlled pharmacological treatment.
- To train and support in the implementation of the hyposodic diet, as it corresponds to Primary Care, as the first level of health care in charge of health promotion and disease prevention.
- Develop guidelines/questionnaires adapted to the follow-up of hypertensive patients.
- Analyze the cost/effectiveness of the educational intervention.

Study Methodology

Study design

This is a prospective, single-center, single cohort, observational-EPA-SP study to assess the usefulness of the intervention of

an educational program, which includes the promotion of the hyposodic diet together with the delivery of educational material in poorly controlled hypertensive patients in the primary care setting.

The study will be carried out by a multidisciplinary team where the selection of study participants will be done by means of reviews with the OMI AP Cantabria system and in the daily clinical consultation. We will have the support of the staff of the Hospital Universitario Marqués de Valdecilla (Clinical Pharmacology Service) and IDIVAL for the implementation and management of the project, analysis of the results, and interpretation of the pharmacological data. Likewise, there is a Nephrology specialist who will evaluate the monitoring of sodium and potassium levels in urine.

Study population

Adult patients diagnosed with and under treatment for arterial hypertension.

Selection criteria

Patients will be selected from the primary care center of Astillero, Cantabria (Spain), belonging to the Cantabrian Health Service (SCS) provided that they meet all the inclusion criteria and none of the exclusion criteria described below:

Inclusion criteria

- Patients over 40 years of age.
- Patients with a diagnosis of AHT (according to ESC/ESH 2018 criteria) in PC consultation or by MAPA at the health center.
- On treatment with mono, double or triple antihypertensive therapy.
 - Patients with SBP figures ≥ 140 mmHg.
 - Patients with DBP values ≥ 90 mmHg.
 - Patients with stable antihypertensive treatment or without modifications in treatment at least in the last month.
 - Patients who agree to follow up the study.
 - Patients who have given written informed consent.

Exclusion criteria

- Patients with decompensated heart failure.
- Severe renal failure.
- Decompensated liver disease.
- Taking non-insulin antidiabetic drugs (SGLT2).
- Hypertension of pharmacological origin and other causes.

Treatment description

Single cohort observational prospective project. The educational program interventions carried out by primary care staff to encourage adherence to a low-sodium diet consisting of direct action on the patient and delivery of educational materials will be assessed. The educational intervention will be carried out after the patient's inclusion in the study (baseline) and will be reinforced in all patients in the 3rd month. Compliance and follow-up of the low sodium diet will be done by monitoring urinary sodium in the target population, selected according to the selection criteria described in the protocol.

Study variables (main and secondary)

The variables will be analyzed to determine whether the study

hypothesis is fulfilled. To this end, the end points of the study will be determined by analyzing variables that respond to the stated objectives, which are described below:

Primary efficacy variable

•Systolic BP and diastolic BP values. The variation in BP figures before (baseline) and after (3 and 6 months) the intervention will be evaluated.

Secondary variables

- Sodium and potassium levels in 24-hour urine and in isolated urine sample measured at baseline, 3 months and 6 months.
- Antihypertensive pharmacological treatment: variation in the number and type of drugs from the baseline visit to the end of post intervention follow-up (6 months).
- Compliance with the low-sodium diet measured by means of the Survey of salt consumption in patients with hypertension.
- Therapeutic compliance using the Morisky-Green test.
- Quality of life using the EQ-5D questionnaire.

The sociodemographic characteristics of the patient (sex, age) and anthropometric measurements (weight, height) will also be collected as control variables. Throughout the study, adverse events presented by the patient will be recorded independently of their relationship with the educational intervention or with the antihypertensive treatment.

Source of information and data collection

The study will be conducted in primary care consultations, clinical data will be documented in the patient's medical record according to standard clinical practice. Patients included in the study will be anonymized according to the guarantees described in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and its regulation in Spain through the Organic Law 3/2018 of December 5 on the protection of personal data and guarantee of digital rights.

The clinical data of the recruited patients will be included in the data collection notebook (CRD) of the study identified by a numerical code, so that the identifying personal data are dissociated from the clinical data collected for the purpose of the study.

Expected Sample Size and Basis for its Determination

Data handling and statistical analysis

To calculate the sample size, the following parameters were used for the estimation: confidence level of 95%, precision of 5%, proportion of blood pressure control after applying the educational intervention of 75. It was decided to add a further 5% to allow for possible losses due to the absence of complete follow-up, so that the final sample size would correspond to 303 cases. A preliminary analysis (intermediate analysis) will be performed when 50% of the included patients have been included. For the analysis of the main objective, the Student's test will be used, and if the variables follow a nonparametric distribution, Wilcoxon test will be applied.

Limitations of the design, source of information and methods of analysis

The study has been designed as a single cohort in which the

Table 1. Work plan Flow chart.

PROCEDURES	INITIAL PHASE	EXECUTION PHASE				FINAL AND DIFFUSION PHASE
		VISIT 1	VISIT 2 (1 week after visit 1 $\pm$ 3 days)	VISIT 3 (3 months $\pm$ 15 days)	VISIT 4 (6 months $\pm$ 15 days)	
Request for evaluation to CEIm	x					
Informed consent		x				
Assessment of inclusion/exclusion criteria		x				
Physical Examination		x				
BP		x		x	x	
Weight/ Height		x				
Sociodemographic survey		x				
Delivery of diet instructions			x	x*	x*	
Urine sample collection		x		x	x	
Diet follow-up				x	x	
Medication record		x	x	x	x	
Quality of life questionnaires		x		x	x	
Adverse events			x	x	x	
Statistical analysis						x
Publication results						x

*Educational reinforcement

intervention is performed and evaluated and compliance is monitored. Although this design has limitations due to the lack of a control group, the performance of a comparative randomized clinical trial (intervention arm and non-intervention arm) would not be feasible or ethical, since the low-sodium diet is internationally recommended as a measure for the control of arterial hypertension.

Work Plan

The total duration of the study is expected to be of two years. This includes an initial period of 6 months for the submission of the documentation to the Ethics Committee (CEIm) and the request for classification to the corresponding regulatory agencies (AEMPS). The study execution period will be of 13 months in addition to another 5 months, which are estimated for the dissemination of results.

Initial phase (6 months)

Authorization will be requested from the CEIm-Cantabria to carry out the study in the Astillero primary care center and classification to the AEMPS for the designation of the type of observational study. The study protocol will be submitted together with the Patient Information Sheet-Informed Consent.

Execution phase (6 months)

Patients will be selected by means of reviews with the OMI AP Cantabria system in order to subsequently assess, in daily consultation and after presenting the study to the patient, that the candidate meets the inclusion criteria and none of the exclusion criteria. A survey on dietary habits/calculation of salt

intake and recording of the following variables will be carried out: sociodemographic data, blood pressure figures (SBP and DBP) with a blood pressure monitor exclusively for this study in order to standardize measurements and avoid deviations in the instrument itself, anthropometric measurements (weight, height), antihypertensive drugs (number and type), assessment of therapeutic compliance (Morisky-Green test) and completion of the quality of life questionnaire.

If the patient meets the criteria, a 24-hour urine sodium sample will be taken and another isolated urine sample will be sent to the laboratory for analysis. At this time, a detailed explanation of the hyposodic diet will be given with educational material and written instructions.

The patient will be followed up at 3 and 6 months by means of a consultation review to assess the variables BP, weight, urine sodium levels plus verification and reinforcement of the diet by means of the survey and records of the changes in the hypertensive treatment. All the data obtained for this study will be collected in a collection notebook designed for this study.

Final phase (4 months)

Statistical analysis of the results obtained will be performed. Practical guidelines will be established on the basis of the surveys carried out during the study.

Dissemination phase (5 months)

Publication of results in scientific journals related to the pathology under study and presentation of results in Primary Care congresses.

Ethical aspects and protection of the participating subjects

The study will be conducted in accordance to the principles of the Declaration of Helsinki adopted by the 18th World Medical Assembly, Helsinki, Finland in 1964 and amended in Tokyo (1975), Venice (1983), Hong Kong (1989), South Africa (1996), Edinburgh (2000), Washington (2002), Tokyo (2004), Seoul (2008) and Fortaleza (2013); and the Laws and Regulations in force in Europe and Spain.

Because the study will be performed under conditions of routine clinical practice, it will not have any direct medical benefit or risk for the patient, since it does not involve any change in his or her treatment, nor in other aspects of his or her usual daily activities. The patient must give consent before being admitted to the observational study. The physician should explain the nature, purpose and possible consequences of the study in a way that is understandable to the patient. The information provided by the physician should also be recorded. The subject of the study will give his/her consent by signing the corresponding form, which should also bear the signature of the investigator. The investigator will not initiate any research corresponding to the study until he/she has obtained the patient's consent.

In order to guarantee the confidentiality of the data of the patients participating in the study, only the investigator and his team of collaborators, the representative of the sponsor who will carry out the monitoring tasks, the auditor in case the study undergoes an audit, the CEIC and the Health Authorities will have access to the data.

The processing, communication and transfer of personal data of all participating subjects will comply with the provisions and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and its regulation in Spain through Organic Law 3/2018 of 5 December on the protection of personal data and guarantee of digital rights.

During the course of the study, all documents related to the study will be located in a secure area of the center. The file containing patient identifiable data will be the responsibility of the investigators and no file used for data collection or analysis will carry patient identifiable data. The database generated by the study will not contain any patient identification. Thus, patients will not be identifiable, since this database will not contain information on patients' initials, history numbers or any other identifying information relating to these patients.

The performance of this study does not interfere with the prescribing habits of the antihypertensive drug(s) that the patient receives, nor is the drug the main object of the study. Said drug(s) will be prescribed and dispensed based on the authorized conditions of use and usual clinical practice without the observational study modifying the usual prescribing habits.

Adverse Event Management and Reporting

The study sponsor will report suspected serious unexpected adverse reactions detected in the study based on the following criteria and definitions: Adverse Reaction: any response to a drug that is noxious and unintended, occurring at doses normally applied in humans for the prophylaxis, diagnosis, or treatment of disease, or for the restoration, correction, or mod-

ification of physiological functions. This term also includes all harmful clinical consequences resulting from drug dependence, abuse and misuse, including those caused by use outside authorized conditions and those caused by medication errors.

Serious Adverse Reaction: Any adverse reaction that results in death, may be life-threatening, requires hospitalization of the patient or prolongation of existing hospitalization, results in significant or persistent disability or incapacity, or constitutes a congenital anomaly or birth defect. For reporting purposes, suspected adverse reactions that are considered medically important, even if they do not meet the above criteria, such as those that put the patient at risk or require intervention to prevent any of the above outcomes, will also be treated as serious. Likewise, for reporting purposes, all suspected transmission of an infectious agent through a drug will be treated as serious.

Unexpected adverse reaction: Any adverse reaction whose nature, severity or consequences are not consistent with the information described in the technical data sheet. The notification will be made to the Pharmacovigilance Center of Cantabria through the usual channels for spontaneous notification by healthcare professionals (Yellow Card), which can be: Paper notification on the usual notification form, i.e. the yellow card that will be sent to the center cited. On-line notification through the web page of the Pharmacovigilance Center of Cantabria, following the instructions given there: <https://saludcantabria.es/index.php?page=centro-de-farmacovigilancia>.

In any of the cases, it will be stated that the notification comes from an observational study, indicating the name and code of the study from which it comes from.

Resources for Carrying out the Study and Assignment of Tasks

In the Primary Care setting, the necessary resources are available to carry out this observational study. In general, the actions on the patients are part of the usual clinical practice, although some measures related to the promotion of changes in lifestyle habits will be reinforced by following the educational program described in this protocol, mainly with the hyposodic diet. The measurement of sodium in urine is not a standardized practice, but it is considered to be of great value in the follow-up of these patients. This practice does not pose a risk for the patient, and, on the contrary, it can be beneficial and translate into an improvement in their quality of life through knowledge and reinforcement of their health education. On the other hand, it can be economically beneficial for the public health system by reducing the number of consultations and adjustments in the treatment of hypertensive patients.

Practical Considerations

Follow-up and final reports

After completion of the study, the principal investigator will prepare a final report for the relevant health authorities and the CEIm.

Dissemination of the results

Based on the above and, more specifically, on the work of Ortega MR. et al (BMJ 2011), which reflects the salt intake in the Spanish population based on the determination of sodi-

um in urine (168 mmol/d=9.8 g of salt per day) and its positive correlation with blood pressure figures. In the present study, we intend to use this biochemical determination in the follow-up of hypertensive patients.

Taking into account that around 50-60% of hypertensive patients are “salt sensitive”, that is, they are patients who suffer elevations in TAS SBP of up to 10 mmHg with sodium intake. In this group of patients, a controlled hyposodic diet together with antihypertensive drugs is an important approach.

We should insist on the implementation of the hyposodic diet from Primary Care through health education on healthy lifestyles and the support of analytical tests, such as urine sodium detection, which help to reinforce therapeutic follow-up, all with the aim of delaying or avoiding the modification of doses and/or an increase in the number of antihypertensive drugs.

The results obtained, both positive and negative, will be published in scientific journals of impact and in scientific meetings related to the subject of the study. Intermediate results that may compromise the reliability of the final trial results will not be publicized. The anonymity of the participants in the study shall be maintained at all times.

Funding

This study is a non-commercial study. A local grant called PRIMARY CARE RESEARCH PROJECTS SUPPORT PROGRAM (PRIM-VAL) 2019 has been received and published in the autonomic Call for Programs to Revitalize Biosanitary Research in 2019.

Competing Interests

The authors declare that they have no competing interests.

Author's Contribution

All persons who met authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take full public responsibility for the content of this protocol. All authors read and approved the final manuscript.

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To cite this article: Blázquez AB, Alconero LL, María del Mar García Saiz . Observational Study to Evaluate the Efficacy of an Intervention with a Low Sodium Diet using Urine Sodium Monitoring in Patients with Arterial Hypertension (AHT) in the Primary Care Setting. *Pharmacology and Pharmacogenomics.*2022; 1(1): 101-106. doi: 10.31488/jpp.101.