ORIGINALES

Classes of antihypertensive drugs and their combination on public health system patients with systemic arterial hypertension

Classes de anti-hipertensivos e sua combinação entre pessoas com hipertensão arterial sistêmica no sistema público

Clases de antihipertensivos y su combinación entre personas con hipertensión arterial sistémica en el sistema público

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ABSTRACT

The article analyzes the prescribed antihypertensive drugs classes and their quantity in daily use in the treatment of patients with systemic arterial pressure in the public health system and the combination between the amount of antihypertensive drugs prescribed and the control of arterial pressure levels in two Brazilian municipalities. This is a descriptive, quantitative approach study, carried out in 2014, with 757 people enrolled in unities of family health strategy at a municipality in Minas Gerais and another in São Paulo. The study was approved by the Research Ethics Committee of the Ribeirão Preto School of Nursing, University of São Paulo, Process no.: 02313012.4.0000.5393. For data collection, validated instruments were used to characterize the sample and to map antihypertensive drugs used. It was found that drug treatment occurs in combination and daily use among people was of more than one drug, in the last week, in Minas Gerais: 201 (55.8%); in São Paulo: 253 (63.7%). Verifying the association among the amount of antihypertensive drugs used, statistical significance was not found. The present data support the conclusion that the antihypertensive prescriptions for the sample are consistent with the guidelines recommended by primary care documents issued by the Ministry of Health.

RESUMO

Objetivou-se analisar as classes de anti-hipertensivos prescritas e a sua quantidade no consumo diário no tratamento da hipertensão arterial sistêmica (HAS) no sistema público e verificar a associação entre a quantidade de anti-hipertensivos prescritas e o controle dos níveis pressóricos em dois municípios brasileiros.

Trata-se de um estudo descritivo de abordagem quantitativa, realizado em 2014, com 757 pessoas cadastradas em unidades de estratégia de saúde da família de um município de Minas Gerais e de São Paulo. O estudo foi aprovado pelo Comitê de Ética em Pesquisa da Escola de Enfermagem de Ribeirão Preto da Universidade de São Paulo, CAAE: 02313012.4.0000.5393. Para a coleta de dados foram utilizados instrumentos validados para caracterização da amostra e para o levantamento das medicações anti-hipertensivas utilizadas.

Constatou-se que o tratamento farmacológico ocorre de forma combinada e o consumo diário entre as pessoas foi de mais de um medicamento na última semana em Minas Gerais, 201 (55,8%) em São Paulo 253 (63,7%). Ao verificar a associação entre a quantidade de medicações anti-hipertensivas não foi encontrada associação estatisticamente significante.

Os dados apresentados permitem concluir que as prescrições de anti-hipertensivos para a amostra estudada estão de acordo com as diretrizes preconizadas pelo caderno de atenção básica do Ministério da Saúde.

Palavras chave: Hipertensão; Anti-hipertensivos; Atenção Primária à Saúde.

RESUMEN

Este estudio analiza las clases de antihipertensivos prescritos y su cantidad en la ingesta diaria en el tratamiento de la hipertensión arterial sistémica (HAS) en el sistema público y la asociación entre la cantidad de fármacos antihipertensivos prescritos y el control de la presión arterial en dos municipios brasileños.

Se trata de un estudio descriptivo de abordaje cuantitativo, realizado en 2014, con 757 personas registradas en las unidades de Estrategia de Salud de la Familia de un municipio de Minas Gerais y São Paulo. El estudio fue aprobado por el Comité de Ética de la Escuela de Enfermería de Ribeirão Preto, Universidad de São Paulo, CAAE: 02313012.4.0000.5393. Para la recogida de los datos fueron utilizados instrumentos validados para caracterizar la muestra y para el levantamiento de las medicaciones antihipertensivas utilizadas.

Se encontró que el tratamiento farmacológico se produce de forma combinada y el consumo diario entre la gente era de más de un medicamento en la última semana, en Minas Gerais, 201 (55,8%), en São Paulo 253 (63,7%). Al verificar la asociación entre la cantidad de medicamentos antihipertensivos no se encontró asociación estadísticamente significativa.

Los datos presentados permiten concluir que las prescripciones de antihipertensivos para la muestra estudiada son consistentes con las pautas recomendadas por el cuaderno de atención primaria del Ministerio de Salud.

Palabras clave: Hipertensión; Antihipertensivos; Atención Primaria de Salud

INTRODUCTION

Systemic Arterial Hypertension (SAH) represents a severe public health problem, being considered one of the main risk factors for cardiovascular diseases and is responsible for high morbidity rates[1]. Arterial pressure (AP) control is essential in reducing its severe complications and, for that purpose, pharmacological and non-pharmacological measures are taken[1].

Non-pharmacological measures, which include changes in life style, are generally indicated to SAH patients[1, 2].

Pharmacological treatment includes several drug classes, which are prescribed taking in consideration the associated comorbidities, effects on target organs, age, family-history and pregnancy. Treatment may be a mono- or a combined therapy[3].

Knowledge of the most prescribed classes of antihypertensive drugs and the daily quantity administered for the treatment of systemic arterial hypertension (SAH) in the public health system are indispensable to redefine public policies in order to evaluate treatment efficacy and to propose appropriate interventions to demands with the aim of improving life conditions and health of people with SAH[4,5].

Drug therapy is a concern both for SAH patients and for health professionals, considering the combined use of antihypertensive drugs. Since this is a study carried out in the public health system, the prescriptions must be in accordance with the "Relação Nacional de Medicamentos Essenciais (RENAME)[6"]. The relevance of this study is expressed by a comparative analysis of antihypertensive drugs prescribed to individuals with medical diagnosis of SAH in two municipalities, in the states of Minas Gerais and of São Paulo, and by evaluating the antihypertensive drugs combination, as per protocols established by the Brazilian SAH Guidelines.

Therefore, the aim of the present study was to analyze the classes of antihypertensive drugs prescribed and the quantity of daily intake in the treatment of systemic arterial hypertension (SAH), in the public health system, and to verify the association between prescribed antihypertensive drugs and the control of AP levels in two Brazilian municipalities.

METHOD

In 2014, 757 individuals took part in an epidemiological, descriptive, crossover study, with quantitative approach, which was based on a sample calculated by the *Open Epi Version 2*. Participants were enrolled in unities of family health strategy (UFHS) in two municipalities, one in the state of Minas Gerais and another in the state of São Paulo.

The current study is an extract of the network developed between two public universities, in the states of Minas Gerais and São Paulo, entitled: "Life quality regarding health among hypertension patients enrolled in Units of Family Health Strategy".

Validated tools for the characterization of the sample, which comprises sex, age, marital status, familiar monthly income, education, occupation and one question related to the drug in use and the quantity of drugs taken on a daily basis, were used for data collection. Acceptance criteria included: being enrolled in the UFHS, age of 18 or above, and having the diagnosis of SAH. Refusal criteria included: Individuals who were unable to answer the questions or who were not found at home after three visits.

Data were collected in between March, 2013 and August, 2014, by interviewers which included students from the 8th period of the Nursing Graduation Course and the nurses who had been trained by researchers responsible for the study.

Measurement of AP value at the data collecting time was carried out with an automatic OMRON® HEM-742 tool. This equipment is validated by the *Association for the Advancement of Medical Instrumentation* and by the *British Hypertension Society*[1] protocols. For the measurement of AP, the recommended VI Diretrizes Brasileiras de Hipertensão[1] (VI Brazilian Hypertension Guidelines) were used. AP was measured three times in a sequence for each individual, with a minimum interval of 1 minute between measurements, taking as reference the arm with the higher value. AP mean was obtained by taking in consideration the last two measurements taken from each individual with SAH. SAH patients with AP values of <140/90 were considered under control, in accordance with Brazilian and international guidelines[1, 7-9].

In order to analyze data an electronic spreadsheet was prepared, data being saved with the use of *Excel* program and the collected data were typed, in double entry. Next, consistency of the fields was checked, by resuming the original interview, when necessary, for correction. For the statistical analysis, *SPSS software* (*Statistical Package for the Social Sciences),* version 15.0, was used. A 5% significance level was considered in every analysis. To evaluate the association among the quantity of drugs used and the pressure levels, M*ann-Whitney* test was used*.* Test choice was based on the analysis by the *Shapiro-Wilk* test to verify the variable 'normality', with the purpose of using parametric or non-parametric tests. This way, it was decided to use non-parametric test once the sample did not show normal distribution as per the normality test.

The study was approved by the Comitê de Ética em Pesquisa from the Nursing School of de Ribeirão Preto, University of São Paulo (EERP/USP), Process: 02313012.4.0000.5393. Participants were instructed to sign the Termo de Consentimento Livre e Esclarecido, and were assured anonymity and the right to quit at any time.

RESULTS

This study showed a larger number of female participants - 486 (64.2%) – than of male participants - 271 (35.8%). As far as age is concerned, six (0.8%) were in between 19 and 29 years of age; 12 (1.6%), in between 30 and 39 years; 68 (8.9%), in between 40 and 49 years; 161 (21.3%), in between 50 and 59 years, and, 510 (67.4%) were 60 or above. Concerning marital status: 70 (9.2%) were single; 446 (58.9%) were married; 64 (8.5%) were separated, and 177 (23.4%), widowed.

Concerning familiar monthly wage: 53 (7.0%) received less than a minimum salary; 327 (43.2%) received from one to two minimum salaries; the others got more than two minimum salaries, and 57 (7.5%) could not tell.

Concerning education: 76 (10.0%) were illiterate; 463 (61.2%) had not finished elementary school; 97 (12.8%) had finished elementary school; 29 (3.8%) had not finished middle school; 59 (7.8%) had finished middle school, and 33 (4.4%) had finished higher education.

Concerning occupation: 344(45.4%), had income and 413 (54.6%) did not have an income.

Considering duration of SAH diagnosis, according to personal reports, the mean time for 212 (28%) of the participants was of 10 years. Now of the data collection, arterial

pressure was out of the standard in 200 (50.4%) of participants in Minas Gerais, and in 202 (56.1%) of participants in São Paulo (Table 1).

Table 1. Distribution of participants with Systemic Arterial Hypertension (n=757) as per variable 'arterial pressure classification'. Brazil, 2014.

VARIABLE	São Paulo		Minas Gerais		TOTAL	
Arterial pressure classification	**n**	**%**	**n**	**%**	**n**	**%**
Excellent	44	12.2	39	9.8	83	11
Normal	55	15.3	70	17.6	125	16.5
Prehypertension	59	16.4	88	22.2	147	19.4
Stages of Hypertension 1, 2 and 3	202	56.1	200	50.4	402	53.1
TOTAL	360	100	397	100	757	100

It was observed that the pharmacological treatment occurs in a combined way, and that, in the last week, the daily intake was of more than one drug in Minas Gerais: 201 (55.8%); and 253 (63.7%) in São Paulo (Table 2).

Table 2. Distribution of participants with systemic arterial hypertension (n=757) as per variable 'quantity of antihypertensive drugs in daily use in the last week'. Brazil, 2014.

VARIABLE	São Paulo		Minas Gerais		TOTAL	
Quantity of antihypertensive drugs used*	**n**	**%**	**n**	**%**	**n**	**%**
One	159	44.2	144	36.3	303	40.0
Two	102	28.3	175	44.1	277	36.6
Three or more	99	27.5	78	19.6	177	23.4
TOTAL	360	100	397	100	757	100

* Only participants with systemic arterial hypertension that used drugs on a daily basis and there was more than one answer by participant.

Table 3 shows the association between the quantity of antihypertensive drugs used and the arterial pressure classification, as per the distribution of participants with systemic arterial hypertension. The *Mann-Whitney* statistical test showed that the association is not statistically significant in these variables (p=0,615).

Table 3. Association between the quantity of antihypertensive drugs used and the classification of arterial pressure as per the distribution of participants with systemic arterial hypertension (n=757). Brazil, 2014.

VARIABLE	ANTIHYPERTENSIVE DRUGS USED							
AP Classification	None		One		Two or more		TOTAL	
São Paulo	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Excellent	15	9.4	15	14.7	14	14.1	44	12.2
Normal	22	13.8	18	17.6	15	15.2	55	15.3
Prehypertension	28	17.6	15	14.7	16	16.2	59	16.4
Stages of Hypertension 1, 2 and 3	94	59.1	54	52.9	54	54.5	202	56.1
TOTAL	159	100	102	100	99	100	360	100

AP Classification	None		One		Two or more		TOTAL	
Minas Gerais	n	%	n	%	n	%	n	%
Excellent	12	8.3	18	10.3	9	11.5	39	9.8
Normal	24	16.7	33	18.9	13	16.7	70	17.6
Prehypertension	31	21.5	36	20.6	21	26.9	88	22.2
Stages of Hypertension 1, 2 and 3	77	53.5	88	50.3	35	44.9	200	50.4
TOTAL	144	100	175	100	78	100	397	100

* *Mann-Whitney* test p=0,615

At the Minas Gerais municipality it was observed a predominance of combination between thiazide class of diuretics and the class of angiotensin-converting enzyme (ACE) inhibitors, followed by thiazide diuretics and angiotensin II antagonists, whereas in São Paulo there was a predominance of combination between the thiazide class of diuretics and angiotensin II antagonists, as shown in Table 4.

Table 4. Distribution of participants with systemic arterial hypertension (n=757) as per variable 'antihypertensive class of drugs in daily use in the last week'. Brazil, 2014.

VARIABLES	São Paulo n*	Minas Gerais n*
Monotherapy		
Angiotensin II Antagonist	26	33
Betablockers	13	27
Calcium Channels Blockers	13	9
Thiazide Diuretics	14	11
ACE Inhibitors	61	41
Combination of two antihypertensive drugs		
Angiotensin II antagonists + Thiazide diuretics	25	36
Angiotensin II antagonists + Betablockers	3	19
Betablockers + Thiazide Diuretics	4	21
Betablockers + ACE Inhibitors	17	14
Thiazide Diuretics + ACE Inhibitors	15	42
Combination of three antihypertensive drugs		
Betablockers + Angiotensin II Antagonists + Thiazide diuretics	8	5
Betablockers + Thazide diuretics + ACE Inhibitors	6	6
Thiazide Diuretics + Calcium Channels Blockers + ACE Inhibitors	8	3
Combination of four antihypertensive drugs		
Betablockers + Angiotensin II Antagonists + Thiazide Diuretics + Calcium Channels Blockers	1	3
Betablockers + Angiotensin II Antagonists + Thiazide Diuretics + Loop Diuretics	1	1
Betablockers + Loop Diuretics + Thiazide Diuretics + Potassium-sparing diuretics	3	1
Betablockers + Thiazide Diuretics + Calcium Channels		

Blockers + ACE Inhibitors	3	1
Loop Diuretics + Thiazide Diuretics + Potassium-sparing diuretics + ACE inhibitors	1	1

*Only participants with systemic arterial hypertension that use drugs on a daily basis and there was more than an answer per individual.

DISCUSSION

Data from the present study allowed an analysis of classes of antihypertensive drugs prescribed to SAH patients enrolled in two unities of family health strategy in two municipalities, one in the state of Minas Gerais and another in the state of São Paulo. This enabled the verification of associations of antihypertensive drugs, the comparison of the prescription pattern of pharmacological drug class between the unities of family health strategy, and if it is in compliance with the protocols of the VI Diretrizes Brasileiras de Hipertensão and the effect on pressure levels.

However, such data may not reflect the totality of drugs used by SAH patients, since self-prescribed drugs and those used in the treatment of comorbidities are not taken in consideration.

Regarding age and sex of SAH patients in the sample, the data point to a predominance of female participants in both unities of family health strategy, in the range of 59 years or older. Data from this study corroborate those from national and international research, which compare female to male in the same age range, being considered more vulnerable to health changes, such as falls, multiple diseases, obesity, several dependencies, and, consequently, to the use of several drugs, with a possibility of causing drug interaction and self treatment[4]. Therefore, the knowledge about antihypertensive drugs classes used as well as follow-up and information about risks and possible redundant combinations is important.

Besides, participants 59 years or older usually need two or more drugs for an appropriate pressure control, a thiazide diuretic being prescribed in most cases [3,4].

In relation to marital status, the present study results show a predominance of SAH patients married or living with a partner, both in Minas Gerais and in São Paulo. The presence of a companion may lead to adhesion to drug treatment, thus helping the control of arterial pressure levels. Literature states that health professionals should stimulate the participation of the spouse or partner as a support to the care of this family member in the treatment of SAH and, thus, favor adhesion to the treatment and disease control[10].

In the present investigation, there was a predominance of participants with low familiar monthly income and low level of education. Among Brazilian researches with individuals with SAH, education level and socioeconomical *status* were similar to those presented by this study[11, 12]. The relation between the socioeconomical *status* and the SAH condition has been the object of several reviews. However, the socioeconomical *status* impact on SAH has presented conflicting results among several studies[13]. A recent study concluded that the socioeocnomical limitations are associated with an increase of the AP, and this association is particularly evident in the education level. It is important to identify and monitor SAH among vulnerable groups, in different countries and societies, in order to reduce complication risks[13]. As it deals with people in a chronicle condition and from low income *stratum* the analysis of prescribed drugs

from the list of freely distributed drugs is essential for access to treatment and, consequently, to adhesion to treatment.

Most of the participants in the present study presented arterial pressure out of the reference parameters at the moment of data collection, despite the use of two drugs. The monotherapy in approximately 2/3 of the cases was not enough to reduce pressure levels, which is demonstrated by scientific evidences[1]. Thus, the effectiveness of the prescribed treatment or adhesion by the individual with SAH to the recommended therapy is questioned.

In relation to thiazide diuretics, it was observed that it was the most prescribed class in combination with angiotensin II antagonists at the São Paulo unity of family health strategy, and, in Minas Gerais, it was also the most prescribed class, however, in combination with ACE inhibitors. The results from the present study fit the results of a recent metanalysis, which investigated the use of the main pharmacological classes of antihypertensive drugs in the reduction of arterial pressure and their efficacy in the reduction of cardiovascular events. The authors of this study concluded that the reduction of AP with diuretics was followed by significant reduction of cerebrovascular disease[14]. A national study, which evaluated drug prescription, found as one of the most used classes in the cardiovascular system those that act on the renin-angiotensin system (14.8%)[15]. People with SAH take advantage of the use of this class, which is available at the public health system, as predicted by RENAME and is in accordance with protocols established by the guidelines.

In the present study, the betablockers class was in third place in Minas Gerais and in fourth place in São Paulo. In a national study, it was found that betablockers were the third of the most prescribed antihypertensive drugs[16].

As far as the calcium channels blockers are concerned, they present the same frequency as the betablockers in São Paulo and are fifth place in Minas Gerais. Study carried out in four unities of family health strategy in Marília, São Paulo, also presented similar result, having the calcium channels blockers as a class of antihypertensive drugs less prescribed and there was no significant statistical difference among these unities[4].

Among antihypertensive drugs classes, direct vasodilators is the pharmacological class less prescribed in the unities of family health strategy both in Minas Gerais and in São Paulo. The results of this study corroborate literature that points several side effects related to this class such as water retention and reflexive tachycardia[4]. Therefore, even if they are at public health institutions, its use in SAH patients, mainly among elders, is restricted due to the decrease of metabolic processes, and consequent increase in side effects.

As far as the quantity of antihypertensive drugs and pressure levels are concerned, a significant statistic value was not found. This study results differ from those found in a study carried out in the state of São Paulo, which showed that individuals under monotherapy or with no drug treatment prescribed to control SAH presented a larger incidence of pressure levels higher than 130/80 mmHg, when compared to individuals who used two or more antihypertensive drugs[16].

The fact that the dosage of antihypertensive drugs as well as comorbidities have not been analyzed in this study is a drawback to be pointed out.

CONCLUSION

Considering the results presented, it is concluded that the pharmacological treatment of SAH occurs mainly in monotherapy in the municipality in the state of São Paulo and in combination therapy in the municipality in the state of Minas Gerais. The antihypertensive class most prescribed in São Paulo was the ACE inhibitors, whereas in Minas Gerais it was the combination of ACE inhibitors and thiazide diuretics.

The quantity of prescribed drugs and pressure levels did not show statistical significance.

It was found that antihypertensive drugs prescription in the sample studied is in accordance with the Ministry of Health guidelines, as per the primary care document, provided antihypertensive drugs consumed by public health care individuals are a combination known as effective. In addition, no redundant combinations among antihypertensive drugs classes were prescribed. It is also worth pointing out that prescribed drugs are included in the RENAME list, which is a positive factor to treatment adhesion.

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