



## Effect of a pharmacotherapeutic follow-up program in patients with systemic arterial hypertension

*Efeito de um programa de acompanhamento farmacoterapêutico em pacientes com hipertensão arterial sistêmica*

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### ABSTRACT

Systemic Arterial Hypertension (SAH) is a multifactorial clinical condition with non-pharmacological and/or pharmacological treatment that requires pharmacotherapeutic monitoring in order to manage the health condition. The objective was to evaluate the impact of a pharmacotherapeutic follow-up program of patients with SAH through a quasi-experimental, longitudinal, and prospective study. Twenty-eight patients were evaluated, 50% of which had decompensated blood pressure; the DRPs identified were drug interactions (57.1%), pharmacotherapeutic duplication (28.8%), potentially inappropriate medication use in older adults (38.5%), and non-adherence to treatment (89.3%). Of the NOM identified (Negative Outcomes associated with Medication), 56.2% were related to safety, and 37.5% to effectiveness. After the follow-up, 56.3% of the NOM were resolved, 57.1% of patients adhered to treatment, and there was a reduction in the Systolic Blood Pressure ( $p = 0.010$ ) and Diastolic Blood Pressure ( $p = 0.020$ ). The program proved to be efficient in reducing systemic blood pressure and resolving DRPs and NOM.

**Keywords:** Outcome and process assessment (Health Care). Pharmaceutical services. Systemic arterial hypertension.

### RESUMO

A Hipertensão Arterial Sistêmica (HAS) é uma condição clínica multifatorial, com tratamento não-farmacológico e/ou farmacológico, que necessita de acompanhamento farmacoterapêutico para gestão da condição de saúde. O objetivo foi avaliar o impacto de um programa de acompanhamento farmacoterapêutico em pacientes com HAS, através do estudo quase-experimental, longitudinal e prospectivo. Foram avaliados 28 pacientes, 50% estavam com pressão arterial descompensada, os PRM (Problemas Relacionados à Medicamentos) identificados foram interações medicamentosas (57,1%), duplicidade farmacoterapêutica (28,8%), medicamentos potencialmente inapropriados para idosos (38,5%) e não adesão ao tratamento (89,3%). Dos RNM (Resultado Negativos associados à Medicação) 56,2% relacionavam-se à segurança e 37,5% à efetividade. Após o acompanhamento, 56,3% dos RNM foram resolvidos, 57,1% dos pacientes aderiram ao tratamento e houve redução da Pressão Arterial Sistólica ( $p=0,010$ ) e Pressão Arterial



Diastólica ( $p=0,020$ ). O programa mostrou-se favorável na redução da pressão arterial sistêmica e resolução dos PRM e RNM.

**Palavras-chaves:** Avaliação de processos e resultados (Cuidados de Saúde). Cuidados farmacêuticos. Hipertensão arterial sistêmica

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## INTRODUCTION

In the pharmacotherapeutic treatment of SAH, drug administration is related to treatment results. In several situations, the use of polypharmacy is desired to control and treat SAH and its comorbidities, requiring management to prevent Drug Related Problems (DRPs) <sup>1</sup>.

The participation of the pharmacist as an active member of the health team in the care of SAH patients has been strategic to obtain positive results in reducing and controlling the BP (Blood Pressure), and effective in the management of pharmacotherapeutic treatment <sup>2,3</sup>. A meta-analysis study assessed the effect of pharmacist interventions on blood pressure control by comparing usual care (Systolic BP (SBP): -6.3 mmHg; Diastolic BP (DBP): -2.8 mmHg) with pharmacist interventions (SBP -8.5 mmHg; DBP: -4.6 mmHg), demonstrating a noticeable reduction in SBP ( $\leq 7.6$  mmHg) and DBP (-3.9 mmHg) <sup>4</sup>.

With the available pharmaceutical clinical services, the pharmacist can integrate the health team and intervene in patient care and treatment optimization. The pharmacist-patient-health team collaboration allows achieving therapeutic goals in the treatment of SAH <sup>5</sup>.

Pharmaceutical clinical services, specifically the pharmacotherapeutic follow-up of patients, have proven effective in improving the safety and quality of drug therapy and controlling blood pressure levels in SAH patients <sup>5</sup>. In view of the potential beneficial effects, there is still a shortage of data related to studies in the São Francisco Valley region. This study aimed to assess the impact of a pharmacotherapeutic follow-up program of SAH patients in the Sub-Middle São Francisco Valley.

## METHODS

### DESIGN AND PLACE OF STUDY

The study consisted of a quasi-experimental, longitudinal, prospective design with pre- and post-intervention assessment with a single group, without variable matching, in addition to a control group. The study was conducted at the Polyclinic of the Federal University of São Francisco Valley (UNIVASF), located in Petrolina-PE, from May 2018 to October 2019.

## SELECTION OF PARTICIPANTS

Twenty-eight individuals of both sexes, with age  $\geq 18$  years, residing in the Sub-Middle São Francisco Valley region, diagnosed with SAH, and using at least one medication were included in the study. The non-probabilistic convenience sampling method was adopted. Individuals with severe complicated diseases, cognitive impairment, lack of interest, inability to answer and/or respond to the consultations, and pregnant women were excluded.

## PHARMACOTHERAPEUTIC FOLLOW-UP PROGRAM

The program is conducted through weekly consultations, comprising four consecutive months per patient. In the first consultation, with an average time of 50 minutes, the demographic data, clinical parameters, and pharmacotherapeutic profile were recorded in the medical record of the patient.

In the second consultation, patients received the first health education intervention regarding their knowledge of health problems and the difficulties and possible DRPs and NOM reported and identified in the initial consultation. Patients received a dosing schedule for the prescribed medications used, containing their intake times. The third and fourth consultations consisted of the assessment of the interventions performed.

The dosing schedule for drug administration, the demonstration of the use

of devices for drug administration or monitoring health parameters, besides folders, videos, and possible referrals to health professionals were used as a procedure for the interventions.

## DATA COLLECTION AND EVALUATION

### Clinical outcomes

The BP (reference value:  $<140/90$  mmHg) and random capillary blood glucose (CBG) (reference value:  $<180$  mg/dL) were evaluated as clinical outcomes<sup>6,7</sup>. BP was measured twice using a stethoscope and an aneroid sphygmomanometer, and the mean was calculated and recorded. In cases of doubt, a third measurement was performed by the researcher. CBG was assessed using a calibrated glucometer.

### Characterization of pharmacotherapy

Consisted of the collection of data such as the name of prescribed and non-prescribed drugs used, pharmaceutical formulation, posology, and therapeutic indication. For that purpose, the patient was requested to take to the consultation all drugs used and prescriptions.

The pattern of drug use was analyzed by the Anatomical-Therapeutic-Chemical Classification System (ATC)<sup>8</sup> and by the pharmacotherapy indicators that could be characterized as possible DRPs:

- Therapeutic duplication;
- Potential drug interactions, using Micromedex®;
- Inappropriate medications for older adult patients (PIM), using Beers criteria<sup>9</sup>;
- Treatment adherence, through the Four-Item Morisky-Green-Levine Medication Adherence Scale (MMAS-4), considering scores from 0 – 3 as non-adherent and 4-point scores as adherent<sup>10,11</sup>.

The negative outcomes associated with medication (NOM) were classified using the Dáder model, which categorizes them according to Necessity, Effectiveness, and Safety<sup>13,14,15</sup>.

#### ETHICAL ASPECTS

The project met all ethical requirements according to the Resolution of the National Health Council (CNS) n° 466/2012 and was approved by the Research Ethics Committee of the Federal University of São Francisco Valley (CEP / UNIVASF) under the protocol number 2.472.869. All participants had access to the Informed Consent Form (TCLE) for reading, full understanding, signature, and agreement to participate in the research.

#### STATISTICAL ANALYSIS

The collected data were analyzed statistically with the Statistical Package for Social Science (SPSS 20) and subjected to

descriptive analysis and analytical evaluation. The normality of the data was assessed by the Kolmogorov-Smirnov test, the pre- and post-intervention clinical outcomes were assessed by the paired t-test, and the effect size was measured using Cohen's *d*. Significant associations were considered for the value of  $p < 0.05$ .

#### RESULTS

The data of the 28 patients were evaluated, revealing a higher prevalence of the female sex (67.9%). Age ranged with a mean of  $59.5 \pm 12.1$  years, with the majority of participants with age from 35 to 59 years (53.6%).

The pre-intervention clinical profile of the participants was obtained in the first consultation. Regarding anthropometric measurements, weight varied from 52.6 to 100.4kg, with a mean of  $81.5 \text{kg} \pm 12.2$ ). According to the BMI (body mass index), 73.3% of the adults and 76.9% of the elderly were above the ideal weight.

The SBP values varied from 110 to 180 mmHg, while the DBP values varied from 70 to 100 mmHg (Table 1). The SBP mean was  $136.7 \pm 14.3$  mmHg, and half of the sample (50.0%) was above the clinical goal ( $\geq 140$  mmHg). On the other hand, 67.9% had DBP within the clinical goal ( $< 90$  mmHg), with a mean of  $85.1 \pm 9.6$  mmHg. CBG varied from 87 to 266 mg/dL, with a mean of  $133.9 \pm 43.1$  mg/dL; for 89.3% of patients, the CBG was  $< 180$  mg/dL.

**Table 1.** Clinical profile of SAH patients in the study (N=28) at the first consultation. Petrolina, Pernambuco, Brazil, 2020

VARIABLES	N	%
<b>SBP (mmHg) (136.7±14.3)</b>		
<140	14	50.0
≥140	14	50.0
<b>DBP (mmHg) (85.1±9.6)</b>		
<90	19	67.9
≥90	9	32.1
<b>CBG (mg/dL) (133.9±43.1)</b>		
<180	25	89.3
≥180	3	10.7

SBP (systolic blood pressure); DBP (diastolic blood pressure); CBG (capillary blood glucose). N (number); % (percentage).

Source: the author

Regarding comorbidities (Table 2), 83 classifications were identified in total, with a mean of  $3.0 \pm 1.5$  per patient. In addition to the SAH presented by all

patients, the most prevalent comorbidities were dyslipidemias (53.6%), diabetes *mellitus* (39.3%), and anxiety disorder (28.6%).

**Table 2.** Distribution of the frequency of comorbidities of 28 participants. Petrolina, Pernambuco, Brazil, 2020

COMORBIDITY	N	%
<b>SAH</b>	28	100
<b>Dyslipidemias</b>	15	53.6
<b>Diabetes <i>mellitus</i></b>	11	39.3
<b>Anxiety</b>	8	28.6
<b>Insomnia</b>	5	17.8
<b>Thyroid disorders</b>	5	17.8
<b>Glaucoma</b>	2	7.1
<b>Labyrinthitis</b>	2	7.1
<b>Arthritis</b>	1	3.6
<b>Depression</b>	1	3.6
<b>Disc herniation</b>	1	3.6
<b>Heart Failure</b>	1	3.6
<b>Polyneuropathy</b>	1	3.6
<b>Allergic rhinitis</b>	1	3.6
<b>Tremor</b>	1	3.6
Total number of comorbidities	<b>83</b>	
Comorbidities per patient (mean ± standard deviation)	<b>(3.0±1.5)</b>	

Source: the author

Regarding the pharmacotherapy of the group (Table 3), 140 drugs in total were identified. Of these, most of them act in the cardiovascular system (57.8%), followed by the digestive system and metabolism (19.3%), and the nervous system (12.9%). Regarding the therapeutic class of the drugs

that act in the cardiovascular system, most of them act specifically in the renin-angiotensin system (20.0%), followed by hypolipidemic agents (12.1%) and diuretics (12.1%). Of the drugs corresponding to the digestive system and metabolism, 15.0% are used to control diabetes.

**Table 3.** Distribution of the therapeutic class of drugs used by the 28 participants, according to the ATC classification. (N=140) - Petrolina, Pernambuco, Brazil, 2020

Therapeutic class of drugs	ATC	%	N
Cardiovascular system	C	57.8	81
Alimentary tract and metabolism	A	19.3	27
Nervous system	N	12.9	18
Blood and blood forming organs	B	2.1	3
Systemic hormonal preparations	H	3.6	5
Sensory organs	S	2.1	3
Genitourinary system and sex hormones	G	0.7	1
Musculo-skeletal system	M	0.7	1
Respiratory system	R	0.7	1

Source: the author

The group under study used 140 drugs of continuous use in total, and the intake varied from one to 13 drugs/day ( $5.0 \pm 2.6$ ) per patient. Of the 28 patients, 18 used five or more medications daily, characterizing polypharmacy in 64.3% of the participants.

Regarding DRPs, with respect to drug interactions, it was verified that the medications used by 16 of the 28

participants (57.1%) presented at least one potential drug interaction ( $3.7 \pm 2.6$  per patient). Eleven therapeutic duplications were identified, involving four types of clinical conditions in eight patients, with a frequency of 28.8%. Four Potentially Inappropriate Medications (PIM) in use by five participants were also identified, with a frequency of 38.5% (Table 4).

**Table 4.** Profile and pharmacotherapeutic problems identified among the participants of the study - Petrolina, Pernambuco, Brazil, 2020

<b>PHARMACOTHERAPEUTIC PROFILE</b>	
<b>Total intake of drugs of continuous use (N)</b>	<b>140</b>
<b>Drugs per patient (mean; SD)</b>	<b>(5.0±2.6)</b>
<5 drugs - N(%)	10 (30.7)
≥5 drugs (polypharmacy) - N(%)	18 (64.3)
<b>DRPs</b>	
<b>Frequency of potential drug interactions per patient N (%)</b>	<b>16 (57.1)</b>
Interactions per patient (mean; SD)	(3.7±2.6)
Severe interactions N (%)	<b>24 (33.8)</b>
Moderate interactions N (%)	<b>47 (66.2)</b>
Total number of potential interactions	<b>71</b>
<b>Frequency of Pharmacotherapeutic Duplication N (%)</b>	<b>8 (28.8)</b>
<b>Frequency of use of PIM * N (%)</b>	<b>5 (38.5)</b>

SD (Standard Deviation); \* Older adults in the sample (N=13).

Source: the author

The Dáder method <sup>14,15</sup> allowed identifying 16 NOM as the most frequent, corresponding to the categories of safety (56.2%) and effectiveness (37.5%). Of the total of patients, 11 showed at least one

NOM, with a frequency of 39.3% (0.57±0.83) NOM per patient. Regarding the MMAS-4<sup>10</sup>, non-adherence was identified in 89.3% of participants (Table 5).

**Table 5.** Negative outcomes associated with medication (NOM) and their classifications identified in the group under study, Petrolina, Pernambuco, Brazil, 2020

<b>NOM (Negative outcomes associated with medication)</b>	
<b>CLASSIFICATION</b>	
<b>Necessity N (%)</b>	1 (6.2)
<b>Effectiveness N (%)</b>	6 (37.5)
<b>Safety N (%)</b>	9 (56.2)
Prevalence of NOM	<b>11 (39.3)</b>
NOM per patient (mean ± SD)	<b>(0.57 ± 0.83)</b>
<b>4 points (adherent)</b>	3 (10.7)

Source: the author

As post-intervention outcomes, 56.3% of the NOM identified were

resolved, and 57.1% of non-adherent patients became adherent (Table 06).

**Table 6.** Clinical outcomes after pharmacist interventions in patients with SAH in the group under study, Petrolina, Pernambuco, Brazil, 2020

OUTCOMES AFTER PHARMACIST INTERVENTIONS	
Resolved NOM N (%)	9 (56.3)
Necessity N (%)	0
Effectiveness N (%)	4 (25.0)
Safety N (%)	5 (31.2)
Resolved adherence DRPs N (%)	16 (57.1%)

Source: the author

Regarding clinical outcomes after pharmacist interventions, there was a significant reduction in the SBP from 136.7 mmHg  $\pm$  14.3 to 129.4 mmHg  $\pm$  15.9 (p=0.010), representing a reduction of 5.3% (-7.3 mmHg) and a small effect size (d=0.48), and a reduction in the DBP from

85.1 mmHg  $\pm$  9.5 to 80.6 mmHg  $\pm$  7.4 (p=0.020), with a reduction of 5.3% (-4,5 mmHg) and a medium effect size (d=0.53). Furthermore, there was a 6.2% (-8.3mg/dL) reduction in the CBG mean, with a small effect size (d= 0.23), although not significant (p=0.30) (Table 7).

**Table 7.** Comparison of clinical outcomes after pharmacist interventions in patients with SAH in the group under study, Petrolina, Pernambuco, Brazil, 2020

VARIABLES	1 <sup>st</sup> consultation	4 <sup>th</sup> consultation	p	d
SBP (mmHg)	136.7 $\pm$ 14.3	129.4 $\pm$ 15.9	0.010*	0.48**
DBP (mmHg)	85.1 $\pm$ 9.5	80.6 $\pm$ 7.4	0.020*	0.53**
CBG (mg/dL)	133.8 $\pm$ 43.1	125.5 $\pm$ 27.6	0.30	0.23**

\* p < 0.05 (Paired t-test), \*\* Cohen's d.

Source: the author

## DISCUSSION

In a systematic review, it was verified that, in undeveloped countries, the prevalence of hypertension was equivalent to 30.5% for females and 32.2% for males. However, regarding awareness and treatment, women tend to show better numbers, with an awareness prevalence of 52.7% and interest in the treatment of 40.5%. This scenario results from the

greater demand for health services, favoring the diagnosis and control of SAH<sup>15,16</sup>.

With the increase in age, evidence points towards the growth of AH, verifying that, after 50 years, about half of the population presents self-reported hypertension. This increase is explained by physiological alterations that occur with aging, such as increased peripheral vascular resistance, dysfunction of the renin-



angiotensin-aldosterone system, and/or endothelial dysfunction<sup>17,18,19</sup>.

Aging also collaborates to increase the incidence of chronic diseases such as diabetes, being commonly associated with SAH due to the abnormal activation of the sympathetic nervous system by hyperinsulinemia<sup>18,19</sup>. Therefore, in the pharmacotherapeutic follow-up, it was possible to verify that, among hypertensive and diabetic patients (N=11), the difficulty to control AH or glucose could be related to the comorbidities presented by the patients.

The association of diabetes with SAH doubles the cardiovascular risk and requires the care management of both diseases in the same individual as they potentialize microvascular and macrovascular injury, resulting in high cardiovascular and cerebrovascular morbidity since, even in the absence of any cardiovascular manifestation, it is recommended to classify the individual with diabetes as a patient with “high cardiovascular risk”<sup>6,20</sup>.

Normally, about 70% of hypertensive patients do not respond well to monotherapy, requiring drug combination therapy in order to optimize the efficacy of antihypertensive agents while causing minimal adverse effects and cardiovascular risks. This practice shows to be more efficient in controlling blood pressure levels than increasing the dose of drugs used in monotherapy<sup>21</sup>.

Although recommended and showing positive results in the treatment of comorbidities, drug combination increases

the number of drugs used, constituting polypharmacy, and its inappropriate use can result in DRPs such as adverse effects, drug interactions, therapeutic ineffectiveness, and low treatment adherence, as verified in the sample of the study, besides pharmacotherapeutic duplication and PIM<sup>12,22,23</sup>.

The main drug interactions identified were of the moderate type. Moderate interactions suggest that there may occur exacerbation of the clinical conditions of the patient, or the replacement of therapy is suggested (Micromedex). Most drug interactions identified were similar to studies conducted in other regions of Northeastern Brazil<sup>24</sup>.

Pharmacotherapeutic duplication showed a frequency of 28.8%, a value slightly above the one obtained by a study conducted in Rio de Janeiro (2016), which verified 23.6% of duplication in prescriptions when referring to antidiabetic and antihypertensive drugs<sup>25</sup>.

Four drugs were identified in the assessment regarding PIM (glibenclamide, diazepam, clonazepam, and acetylsalicylic acid). The Beers criteria were used for this evaluation as a tool to assist in selecting medications aiming at reducing possible adverse effects and evaluating the quality and patterns of drug use among older adults<sup>9</sup>. Medication use was evaluated regarding the risk-benefit to the patient since, although potentially inappropriate, the clinical need of the patient has to be considered and monitored along with the use.

Treatment adherence was another variable analyzed before the interventions, showing to be the main DRPs and the starting point for interventional practices. In a study conducted with 937 hypertensive Brazilian patients to validate the 8-item Morisky Scale (MMAS-8), the prevalence of high-adherence patients was 20.4%<sup>26</sup>.

In a systematic review with meta-analysis involving 44 prospective studies and a population of 1,978,919 participants, it was identified that the proportion of good adherence for the treatment of cardiovascular diseases varied from 4.9 to 93.3%, differing according to the medication type, with the lowest adherence rates being verified for antihypertensives (59%) and statins (54%)<sup>27</sup>. It is observed that the non-adherence frequency value detected in the present study is within the variation found in other studies, even being considered a high value if comparing the number of individuals studied.

In addition to DRPs, the occurrence of NOM was assessed using the Dáder method<sup>13,14</sup>. The main NOM related to safety were qualitative and related to complaints of adverse reactions, mostly due to DRPs resulting from drug interactions and medication use at wrong times. Adverse reactions also correlated with medication doses, leading to quantitative effectiveness NOM<sup>12,14</sup>.

Another study reveals that patients that were part of a pharmaceutical intervention group with medication management and health education, monitored during six months, showed

positive clinical outcomes regarding blood pressure levels, medication adherence, and DRPs reduction. The study concludes that health education practices are necessary to incentivize pharmacist-patient interaction, promoting a more dynamic care that can contribute to treatment adherence<sup>28</sup>.

The safety NOM were the ones with the highest resolution rate, followed by the effectiveness NOM. On the other hand, it was not possible to resolve the necessity NOM. Regarding the outcome of therapy adherence, 57.1% of non-adherent patients became adherent. This result corroborates the literature findings,<sup>2</sup> in which this rate corresponded to 68.6% of adherent patients. However, such a divergence is related to the difference in the duration of the pharmacotherapeutic follow-up (10 months), while the present study only demonstrates four consultations, which may reflect in the control of SAH, as observed in the follow-up.

The statistically significant reduction in the SBP and DBP ( $p= 0.010$  and  $p= 0.020$ , respectively) corroborates with the individual clinical outcome of the 28 patients, which means an improvement in the blood pressure control of patients. This result was similar to the one verified in the study by Aguiar et al.,<sup>2</sup> which revealed that, after ten months of pharmacotherapeutic follow-up, 57.2% of 35 patients showed better BP control ( $p=0.001$ ). Besides these, other studies showed similar results<sup>3,29</sup>.

The reduction in the SBP and DBP verified in the present study was higher than

in a systematic review that combined non-pharmacological treatments in hypertensive patients with the use or not of medications<sup>30</sup>. The result was a reduction in the SBP (-4.47 mmHg) and DBP (-1.10 mmHg) in a period < 12 months, demonstrating an estimation of reduction in the short term. In turn, the CBG, although not showing a statistically significant value, showed clinical improvement after the interventions.

At the end of the study, it can be seen that the pharmacotherapeutic follow-up provided a significant reduction in the levels of systolic and diastolic blood pressure, in addition to a significant reduction in the capillary blood glucose of the group. Furthermore, the pharmacist interventions also positively impacted pharmacotherapy adherence and resolved most of the NOM identified, resulting in positive clinical outcomes in patients with SAH.

The study revealed some strong points, such as the pioneering role of the Sub-Middle São Francisco region in the Pharmacy field, the adherence of the participants of the study, and the commitment and acceptability of those who remained until the end of the study, demonstrating the importance of resoluteness and the need for more health services directed toward chronic diseases. However, the study also showed some limitations: considering that it approaches a new and little-known service by the population, its disclosure and acceptance faced difficulties, resulting in a small

number of involved patients, and the short duration of the evaluated services was not sufficient to provide statistically significant assessments of all parameters and interventions.

The present study allowed the implementation of the pharmaceutical service in the institution for only one public (patients with hypertension), but future studies aim to expand this service to other groups and increase the demand to overcome some limitations. Therefore, it is expected that the results obtained can contribute to the diagnosis of the situational scenario of the clinical conditions of SAH patients that make use of medications.

## CONCLUSION

The offer of pharmacotherapeutic follow-up resulted in a significant reduction of blood pressure levels, in addition to a reduction in the CBG of the group. Furthermore, the pharmacist interventions improved pharmacotherapy adherence and solved most of the NOM identified.

Also, the potentiality of the results obtained can encourage new studies to analyze the impacts of pharmacotherapeutic follow-up in the clinical picture of patients with other comorbidities, extending the service to other populations in order to positively reflect on their quality of life and the conditioning of self-care for patients in their daily lives.

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