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Use of Residential Blood Pressure Monitoring as a Tool in Pharmaceutical Care – Baseline Assessment of the MINOR Clinical Trial

Uso da Monitorização Residencial da Pressão Arterial como Ferramenta no Cuidado Farmacêutico – Avaliação secundária do ensaio clínico MINOR

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ABSTRACT

Introduction: Hypertension is a chronic condition that requires constant monitoring and adjustment of drug therapy. Home Blood Pressure Monitoring (HBPM) has proven to be an effective tool in this process, allowing for a more accurate assessment of blood pressure outside of the clinical setting. **Objective:** To evaluate the contributions of the use of HBPM devices in the monitoring and evaluation of antihypertensive therapy in patients served by a public clinical pharmacy service. **Methods:** A longitudinal study with secondary analysis was conducted, using the IBM SPSS Statistics software, of the data aggregated to the MINOR Clinical Trial database, registered on ClinicalTrials under number NCT04861727 and approved by the Research Ethics Committee of the Federal University of Bahia (Opinion No. 4.595.144). **Results:** In the initial assessment with HBPM, 22.98% of participants (n=74) presented hypotension, only 15.84% (n=51) presented controlled hypertension, and 61.18% of individuals (n=166) were identified with uncontrolled hypertension. After pharmaceutical interventions, the proportion of patients with hypotension decreased to 20.81% (n=67), the proportion of controlled hypertension increased to 36.34% (n=117), while the proportion of uncontrolled hypertension decreased to 42.86% (n=138). **Conclusion:** The use of HBPM demonstrated positive contributions to the optimization of antihypertensive drug therapy and proved to be a useful tool in the clinical practice of the pharmacist, contributing to adequate blood pressure control, identification of hypotensive users and candidates for deprescribing.
Keywords: Monitoring; Hypertension; Home Blood Pressure Monitoring

RESUMO

Introdução: A hipertensão arterial é uma condição crônica que exige monitoramento constante e ajuste da terapia medicamentosa. A Monitorização Residencial da Pressão Arterial (MRPA) tem se mostrado uma ferramenta eficaz nesse processo, permitindo uma avaliação mais precisa da pressão arterial fora do ambiente clínico. **Objetivo:** Avaliar as contribuições do uso de dispositivos de MRPA no monitoramento e avaliação da terapia anti-hipertensiva em pacientes atendidos por um serviço público de farmácia clínica. **Métodos:** Realizamos uma pesquisa longitudinal com análise secundária, utilizando o software IBM SPSS *Statistics*, dos dados agregados ao banco de dados do Ensaio Clínico MINOR, registrado no ClinicalTrials sob o número NCT04861727 e aprovado pelo Comitê de Ética em Pesquisa da Universidade Federal da Bahia (Parecer nº 4.595.144). **Resultados:** Na avaliação inicial com MRPA, 22,98% dos participantes (n=74) apresentaram hipotensão, apenas 15,84% (n=51) apresentaram hipertensão controlada, e 61,18% dos participantes (n=166) foram identificados com hipertensão não controlada. Após intervenções farmacêuticas, a proporção de pacientes com hipotensão diminuiu para 20,81% (n=67), a proporção de hipertensão controlada aumentou para 36,34% (n=117), enquanto a proporção de hipertensão não controlada diminuiu para 42,86 % (n=138). **Conclusão:** O uso da MRPA demonstrou contribuições positivas para a otimização da farmacoterapia anti-hipertensiva e mostrou-se uma ferramenta útil na atuação clínica do farmacêutico, contribuindo para o controle adequado da pressão alta, para a identificação de usuários hipotensos e candidatos a desprescrição.
Palavras-chave: Monitoramento; Hipertensão Arterial; Monitorização Residencial da Pressão Arterial

Introduction

Systemic arterial hypertension (SAH) represents one of the greatest challenges for public health, with high morbidity and mortality rates and significant costs for health systems. Blood pressure (BP) variability, especially the "white coat effect," hinders accurate diagnosis and may lead to overdiagnosis and overtreatment, compromising the quality of care.[1,2]

Transient variations in BP may have a relevant clinical impact, which in turn can result in misguided decisions based on pressure values that do not reflect the true average. Discontinuation or reduction of the number of medications is often a challenge, since clinical guidelines generally do not provide specific recommendations for drug withdrawal or substitution in these cases.[1,3,4]

Studies have also identified that approximately 20% of participants would have been misdiagnosed or misclassified if only office BP measurements had been considered, a situation that could lead to unnecessary treatment or overtreatment, increasing the likelihood of adverse reactions, and/or failing to properly treat patients with masked hypertension.[5]

Moreover, the white coat effect, a clinical condition in which systolic and diastolic blood pressures measured in the office are higher compared to those recorded at home, also deserves attention, given its association with an increased risk of cardiovascular events and all-cause mortality.[1,2]

On the other hand, home blood pressure monitoring (HBPM) provides a more accurate view of blood pressure levels, complementing clinical measurements and helping identify patterns of blood pressure variability. It also allows the detection of masked hypertension or the white coat effect, facilitating personalized treatment adjustment and increasing adherence, which contributes to optimized hypertension management and reduced cardiovascular complications.[1,2,6]

In the same line, the implementation of pharmaceutical care in Primary Health Care (PHC), which involves the evaluation of medication necessity, effectiveness, safety and adherence, in addition to monitoring and managing drug therapy-related problems, represents a significant advance in the quality of health care. This practice, being more accessible to the population, proves promising in reducing morbidity and mortality associated with the inappropriate use of medications.[7-9]

Thus, HBPM associated with pharmaceutical care is presented as an accessible and effective technology to produce objective and reliable data in the treatment evaluation process, as well as a tool to support health professionals and patients in making shared decisions on pharmacotherapy optimization.

Objectives

Identify the contributions of the use of Home Blood Pressure Monitoring (HBPM) devices in the monitoring and evaluation of antihypertensive therapy in patients assisted by a public clinical pharmacy service.

Methodology

The present study is a longitudinal research with secondary analysis of data aggregated to the baseline database of the MINOR10 Clinical Trial, registered at ClinicalTrials under nº NCT04861727 and approved by the Research Ethics Committee of the Federal University of Bahia, Opinion nº 4.595.144.

For data collection and subsequent analysis, participants included in the study were those aged 60 years or older, diagnosed with arterial hypertension, using antihypertensive drugs, and assisted at a district pharmacy of the municipal health network of Vitória da Conquista, Bahia, between June 2021 and August 2022. Participants with little or no adherence to prescribed pharmacotherapy, or who for any reason did not adequately complete the HBPM procedure, were excluded from the study.

The selection of participants occurred during the dispensing of antihypertensives at the District Pharmacy, conducted by a team previously trained for recruitment. When participants consented, they were scheduled for clinical pharmaceutical care. The consultations took place in a private room, after explanation of the study objectives and signature of the Informed Consent Form (ICF).

During the consultation, pharmaceutical anamnesis was carried out, including the identification of previous health problems, verification of the list of

current medications, and presence of clinical manifestations of hypotension, in addition to office blood pressure measurement, according to the guidelines of the 2020 Brazilian Hypertension Guideline.

All participants underwent HBPM and were previously instructed about the procedure during the consultation. In accordance with the 2018 Home Blood Pressure Monitoring Guideline, they also received a leaflet with written and illustrated explanations about the procedure, as well as a telephone contact number to clarify doubts during the process, if necessary. The Medbem software was used to retrieve HBPM measurements and calculate the mean home blood pressure, excluding the first measurement performed in the office.

After completion of the HBPM, the pharmacist responsible for the consultation evaluated the results of the measurements and considered the physical examination data and clinical conditions of the participant. Based on this, patients were randomized into control and intervention groups through electronic lottery. The control group patients received guidance on lifestyle and health habits, while the intervention group participants received suggestions for changes in pharmacotherapy, when necessary. Additionally, they were given a recommendation letter to be forwarded to the prescriber with the appropriate indications according to their blood pressure levels.

For statistical analyses, continuous variables with normal distribution were assessed using IBM SPSS Statistics software, calculating mean and standard deviation values, and comparisons were performed using Student's t-test.

Results

During the study period, 322 patients were evaluated, of whom 255 (79.19%) were female, with a mean age of 67 years, an average time since hypertension (HTN) diagnosis of 8 years, and using approximately 3 antihypertensive medications.

Table 1. General characteristics of participants at baseline.

		n(%)	SBP – HBPM Mean (SD)	SBP – HBPM Mean (SD)	p-value
Sex					
	Feminino	255 (79.19)	138 (21)	89 (11)	
					0.475
	Masculino	67 (20.81%)	139 (22)	88 (11)	
Symptoms of hypotension					
	Sim	72 (22.36)	103 (5)	71 (2)	
					<0.001
	No	250 (77.64)	149 (9)	93 (7)	
Symptoms of uncontrolled hypertension					
	Yes	191 (59.32)	153 (6)	96 (5)	
					<0.001
	No	131 (40.68)	118 (18)	77 (8)	
Mean office in SBP (Mean±SD)			143±23		
Mean office DPB (Mean±SD)			92±12		
Time since diagnosis (Mean±SD)			8±15		
Age (Mean±SD			67±4		

Legend: **SBP** - Systolic Blood Pressure; **DBP** - Diastolic Blood Pressure; **HTN** - Hypertension; **HBPM** - Home Blood Pressure Monitoring; **M** - Mean; **SD** - Standard Deviation.
Source: Prepared by the authors based on study data.

At the first clinical consultation, 72 patients (22.36%) presented with one or more symptoms of hypotension, and 191 (59.32%) reported symptoms of uncontrolled HTN. After performing HBPM, it was found that the mean blood pressure of patients who experienced hypotension symptoms was 103 mmHg (SD: 5) for systolic blood pressure and 71 mmHg (SD: 2) for diastolic blood pressure. These pressure levels confirmed the condition and highlighted the presence of overtreatment in these participants.

Among patients who presented with symptoms of uncontrolled HTN, mean systolic BP was 153 mmHg (SD: 6) and mean diastolic BP was 96 mmHg (SD: 5), demonstrating confirmation of inadequate treatment for controlling the condition.

After evaluation of baseline HBPM, the participants (N=322) were randomized into control and intervention groups, with 130 (40.4%) patients assigned to the control group. The remaining 192 patients were randomized to the intervention group, of which 37 (11.5%) underwent deprescription or dose reduction, 6 (1.9%) were referred for substitution of antihypertensive pharmacotherapy, and 59 (18.3%) required the inclusion of additional medications or an increase in the dose of the current prescription.

In addition, 59 (18.3%) were identified with White Coat Hypertension (WCH), characterized as participants with elevated blood pressure in the office but normal results in HBPM, and 31 (9.6%) did not have their interventions/referral letters accepted, as identified during the follow-up visit without changes in treatment.

Patients were monitored for a 45-day period and underwent a second HBPM after clinical consultation to verify the effects of the interventions on blood pressure.

The overall mean SBP of the HBPM participants at baseline was 138.48 mmHg (SD: 20.962), which was reduced to 136.77 mmHg (SD: 17.743) after 45 days of follow-up and the implementation of necessary interventions. The overall mean DBP decreased from 88.37 mmHg (SD: 11.242) to 87.00 mmHg (SD: 8.671).

Table 2. Results of blood pressure levels after 45 days of follow-up.

		n(%)	SBP – HBPM Mean (SD)	SBP – HBPM Mean (SD)	p-value
Sex					
	Female	255 (79.19)	136 (18)	87 (9)	0.045
	Male	67 (20.81%)	138 (16)	87 (8)	0.228
Symptoms of hypotension					
	Yes	42 (13.04)	108 (6)	73 (3)	0.004
	No	280 (86.96)	141 (15)	89 (7)	<0.001
Symptoms of uncontrolled hypertension					
	Yes	113 (35.09)	153 (6)	96 (6)	<0.001
	No	209 (64.91)	128 (16)	83 (7)	0.170
Had intervention					
	Yes	67 (20.81)	125 (11)	81 (5)	0.276
	No	255 (79.19)	140 (18)	88 (9)	0.002
Mean office in SBP (Mean±SD)			142±17		
Mean office DPB (Mean±SD)			90±9		

Legend: SBP - Systolic Blood Pressure; DBP - Diastolic Blood Pressure; SAH - Systemic Arterial Hypertension; HBPM - Home Blood Pressure Monitoring; SD - Standard Deviation.
Source: Prepared by the authors based on study data.

Table 3. Comparison between overall mean HBPM values at baseline and after 45 days of follow-up.

	HBPM SBP (Standard Deviation)	HBPM DBP (Standard Deviation)
Baseline HBPM	138.48 (20.962)	88.37 (11.242)
Final HBPM	136.77 (17,743)	87 (8.671)
p-value	0.014	<0.001

Legend: HBPM - Home Blood Pressure Monitoring; SBP - Systolic Blood Pressure; DBP - Diastolic Blood Pressure.
Source: Prepared by the authors based on study data.

At baseline HBPM evaluation, hypotension with or without symptoms was confirmed in 22.98% of participants (n=74), controlled SAH in only 15.84% (n=51) of the monitored patients, and uncontrolled SAH in 61.18% of participants (n=166). After proper recommendations/indications, pharmacist clinical follow-up, and final HBPM assessment, the rate of patients with hypotension decreased to 20.81% (n=67), the proportion with controlled SAH increased to 36.34% (n=117), and the rate of patients with uncontrolled SAH decreased to 42.86% (n=138).

Discussion

The results of this study within the scope of clinical consultations, with the implementation of necessary interventions to reduce blood pressure levels in patients without adequate BP control, showed improvements in those under overtreatment and maintenance in patients who already presented clinical control.

Studies assessing pharmaceutical care in its different fields of practice suggest positive outcomes of clinical practice in relation to patient health outcomes, aiming at increased positive prognoses and reduced medication use, morbidity and mortality, and physiological parameters.[11,12]

Interventions carried out through the identification of uncontrolled blood pressure levels in patients monitored at home showed an effective decrease in BP values when comparing measurements prior to monitoring and after follow-up by professionals from the public clinical pharmacy service, obtaining residential measurements over seven days at baseline and at the end of follow-up.

HBPM is a monitoring method used in several countries, aiming to improve therapeutic adherence, increase hypertensive patients' awareness of their condition, and assist in the diagnosis of hypertension and its consequences.[5] By analyzing the BP profile before and after home monitoring in the evaluated groups, it is possible to identify the importance of pharmaceutical follow-up associated with techniques such as HBPM, since many patients present alterations often accompanied by clinical symptoms that aid in identifying abnormalities.

However, some participants cannot detect their condition due to lack of evident symptoms, which negatively impacts their health, such as the development of target organ damage and, in cases of hypotension, an increased risk of falls. For this reason, it is important that patients with chronic conditions, especially older adults, gain knowledge and awareness of their health status through techniques such as HBPM, allowing them to contribute to control by undergoing adequate treatment.

Symptoms of hypotension were characterized as dizziness, blurred vision, tremors, asthenia, palpitations, syncope, headache, mental confusion, and/or falls. Hypotension was only confirmed after correct HBPM performance, considering values equal to or below 120/70 mmHg. Symptoms of uncontrolled SAH were specified as chest pain, headache, and/or dizziness, with uncontrolled hypertension confirmed by office BP and HBPM values equal to or above 140/90 mmHg.[1,2]

When analyzing the profile of patients subjected to interventions, it is possible to affirm that all participants were elderly and used around three medications. Many of them presented hypotension symptoms during the first consultation, highlighting overtreatment related to polypharmacy and a possible need for deprescription. Some trials have shown polypharmacy prevalence ranging from 12% to 37% in the evaluated groups, confirming polypharmacy as a public health problem. The authors found that age, diagnosis of chronic diseases, and access to health services are the main risk factors associated with polypharmacy.[13]

Thus, after evaluating the results and implementing the necessary interventions, significant changes were observed in BP levels, as the num-

ber of patients with hypotension and uncontrolled SAH decreased considerably, while the number of patients in the good/optimal BP range substantially increased. This highlights the importance of reducing the number of elderly patients under excessive treatment and consequently decreasing fall risk associated with polypharmacy.

The results indicate the contribution of pharmacists' participation in Primary Health Care, showing significant clinical impacts and contributing to reduced demand on health services through follow-up of patients using continuous medication and subsequent optimization of their treatments.[13]

Some studies have shown that pharmacist participation in the multidisciplinary team is cost-effective and ensures benefits and improved quality of care provided to patients.[14] This follow-up, associated with monitoring techniques such as HBPM incorporated into clinical routine, improves hypertension control and prevents overtreatment or inadequate treatment.[5]

In Brazil, HBPM is not yet included as a procedure integrated into Primary Health Care within the public system. However, results from ongoing studies demonstrate the method's effectiveness for controlling BP levels in patients with abnormal blood pressure.[5] Currently, the gold standard procedure is ABPM (Ambulatory Blood Pressure Monitoring), but it requires specialized professionals, has low availability in the system, and incurs high costs for public health in Brazil.[15]

The limitations of this study include the short follow-up period, as some studies have shown that BP monitoring associated with HBPM achieved significant reductions in BP over a period of approximately 6 to 12 months.[16,17] Other limitations were the self-measurements performed by patients, which are subject to errors, as well as pharmacists' knowledge and techniques during follow-up, and the sample being concentrated in a single care unit.

Conclusion

The use of HBPM associated with pharmaceutical care demonstrated positive contributions to optimizing antihypertensive pharmacotherapy and proved to be a useful tool for adequate hypertension control, identification of hypotensive patients and candidates for deprescription, as well as patients with the white coat effect in Primary Health Care.

Author's contributions
PMM, PRC, ECA, KCA, and PMS participated in the conception and design of the study. PMM, MGO, and PMS performed data analysis and interpretation and drafted the manuscript. PRC, ECA, KCA, MFM, JAD, and SMP actively contributed to the critical review of the manuscript. All authors contributed to and approved the final version of the article.

Conflicts of interest
No potential conflict of interest relevant to this article was reported.

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Data Availability
The data will be made available upon request to the corresponding author.

Responsible
Lindemberg Assunção Costa

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