

Difficulty in taking medication and stroke among older adults with systemic arterial hypertension: the Fibra Study

Dificuldade em tomar medicamentos e acidente vascular encefálico em idosos com hipertensão arterial sistêmica: Estudo Fibra

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Abstract *This article aims to investigate whether difficulty in taking medication is associated with stroke among older adults with Systemic Arterial Hypertension (SAH) and to explore their association with living arrangements. Cross-sectional study was based on 3,502 older adults with SAH from the four universities pole of Frailty in Brazilian Older People (Fibra) Study, Brazil, including 14 municipalities of the five Brazilian regions. We used the medical diagnosis of stroke and difficulty in taking medications (self-reported difficulty and financial difficulty affording prescribed medications). Multivariate analysis was performed using logistic regression. Differently from women, older men with SAH, which report difficulty in taking medication (unintentional non-adherence), have higher odds of stroke. When stratified by living arrangements, those living with a partner have even higher odds of stroke compared to those without difficulty in taking medication and living alone. None association was found for difficulty affording prescribed medication for both men and women. Unintentional difficulty in taking medication plays a role in SAH treatment among men. Primary care strategies for controlling blood pressure should not be focus only on patients but targeting spouses as well.*

Key words *Activities of daily living, Aged, Hypertension, Medication adherence, Stroke*

Resumo *O objetivo deste artigo é investigar se a dificuldade em tomar medicamentos está associada ao acidente vascular encefálico (AVE) entre idosos com hipertensão arterial sistêmica (HAS) e explorar esta associação com arranjos familiares. Estudo seccional baseado em 3.502 idosos com HAS dos quatro polos do Estudo Fibra, Brasil, incluindo 14 cidades das cinco regiões brasileiras. Foi usado o diagnóstico médico de AVE e a dificuldade em tomar medicamentos (dificuldade autorrelatada e dificuldade financeira). Utilizou-se a regressão logística na análise multivariada. Diferentemente das mulheres, homens com HAS que relataram dificuldade em tomar medicamentos (não adesão não intencional) apresentam maior chance de ter AVE. Quando estratificado por arranjos familiares, homens que moravam com o cônjuge apresentaram chance ainda maior de ter AVE, quando comparados com aqueles sem dificuldade em tomar medicamentos e que vivem sozinhos. Nenhuma associação foi encontrada para dificuldade financeira, tanto para mulheres quanto para homens. Dificuldades não intencionais em tomar medicamentos têm um papel importante no controle da HAS entre homens. Estratégias de controle da pressão arterial realizadas na atenção primária não devem focar apenas nos pacientes, mas nos cônjuges destes pacientes.*

Palavras-chave *Atividades cotidianas, Idoso, Hipertensão, Adesão à medicação, Acidente vascular cerebral*

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Introduction

Epidemiological and demographic transitions have been occurring particularly fast in Brazil¹, urging the need for public policies to promote control and preventive care of chronic conditions. Systemic arterial hypertension (SAH) is a highly prevalent chronic condition among adults^{2,3} and older adults⁴ in Brazil. It is one of the main causes of premature morbimortality^{5,6}. Yet, its treatment is one of the most common interventions in Primary Care. Although previous research shows decreasing prevalence trends², its prevalence persists remarkably high among adults, over one-third³, and among older adults, nearly 50%⁴.

Antihypertensive medications are one of the main therapies that started since the first stage of the disease⁷, along with non-pharmacological interventions. Improving blood pressure (BP) has been indicated as a health priority to avoid complications, such as stroke (and its sub derivations, such as mini-stroke), and decrease mortality⁶. Stroke is one of the most common causes of death worldwide that presents a major lifetime risk among adults with SAH⁸. Moreover, poor medication adherence among patients with SAH leads to a 27% higher risk of stroke⁹.

Some of the greatest barriers for achieving BP control are the failure to prescribe antihypertensive medication¹⁰ and the lack of adherence to medication prescriptions (adequate and regular intake)^{10,11}. Forty-four percent of both physicians and patients placed great importance on medication adherence¹². The literature shows that one of the most common difficulties for not taking medication regularly is running out of medicine^{11,13}, most of the time due to poor financial condition¹⁴. However, it is important to add that the National Health System (Sistema Único de Saúde, SUS) in Brazil provides freely or lower-priced antihypertensive medications when the patient has a prescription. Therefore, other factors might decrease pharmacological compliance. In Brazil, pharmacological compliance is around 59% among patients with SAH¹³, inversely associated with age, consulting with a physician less than once a year¹⁵, health beliefs^{13,16}, side effects¹³, regular alcohol consumption, no previous myocardial infarction¹⁵, and polypharmacy¹⁴. Considering data from Barueri and Cuiabá, municipalities in Brazil, only 31.7% of older adults who report a diagnosis of SAH have their BP under control¹⁷.

Nevertheless, patients may present an unintentional non-adherence, described as a passive

process whereby they fail to adhere to prescribing instructions through forgetfulness, carelessness, or circumstances out of their control¹⁸. Practical difficulties in taking medications are an activity measured commonly in epidemiological studies, classified as an instrumental activity of daily living (IADL). It is one example of unintentional non-adherence. According to the Brazilian National Health Survey¹⁹, 31.8% of older Brazilian adults aged 65 and over report difficulty in taking medications by themselves. To the best of our knowledge, no previous study has investigated the impact of unintentional non-adherence drug treatment due to difficulty in taking medications on stroke among older adults with SAH. It is possible that not taking medications properly by themselves may negatively impact stroke when there is not an available person to help. Therefore, this study aims to investigate whether difficulty in taking medication is associated with stroke among older men and women with SAH and to explore their association with the living arrangements.

Methods

Data source

We conducted a cross-sectional analysis based on the Frailty in Brazilian Older People (Fibra) Study's participants. The Fibra Study is a multi-center network conducted in Brazilian municipalities of the five Brazilian regions, including Barueri (SP), Belém (PA), Belo Horizonte (MG), Campinas (SP), Cuiabá (MT), Ermelindo Matarazzo (SP), Fortaleza (CE), Ivotí (RS), Juiz de Fora (MG), Parnaíba (PI), Poços de Caldas (MG), Recife (PE), Ribeirão Preto (SP) e Santa Cruz (RN). The sample size in each municipality was calculated to achieve 50% of determined characteristics, according to the population total number of the municipality. It was a two-stage cluster sample design where: (1) the census tracts of the Instituto Brasileiro de Geografia e Estatística (IBGE – Brazilian Institute of Geography and Statistics) were randomly selected; (2) regarding the older adult population size in the selected census tracts, we set the minimum number of interviews in both census tracts and localities. All households in the selected census tracts were visited, and potential participants were invited to participate until we achieve the minimum number of interviews in that area.

Inclusion criteria of the Fibra Study were being at least 65 years old, being community-dwell-

ing and having Mini-Mental State Examination (MMSE)²⁰ score higher than 17. According to Brucki et al.²⁰, the median score among illiterate older Brazilian adults is 18, considering a population-based sample of older adults aged 65 years and over. Participants were excluded whether they have been showing stroke sequel, Parkinson disease, using a wheelchair and being bedridden²¹. Data was collected in 2008/2009 by interviewers trained previously.

For this analysis purposes, only those who reported medical diagnoses of SAH were included. Due to the unavailability of objective measures of BP control, it was not measured directly. However, self-reported SAH has reasonable validity among older adults in Brazil, with an estimated sensitivity of 77% and specificity of 93% compared to clinical diagnosis and moderate concordance (Kappa = 0.59, $p < 0.001$)²².

Of the 6,762 older adults who took part in the Fibra Study, 3,622 had medical diagnosis of SAH. Among those, 3,502 (96.7%) had full information on studying variables and were included. The flow of participants along with the reasons for exclusion is shown in Figure 1. Those excluded tended to be younger ($p = 0.01$), and take a lower number of medication ($p < 0.001$).

Ethics approval and informed consent

All participants signed the informed consent. The Fibra Study has been approved by the ethics committee of the four universities that supported the study (Universidade Federal de Minas Gerais, Universidade Estadual de Campinas, Universidade de São Paulo, and Universidade do Estado do Rio de Janeiro).

Measures

The study's outcome variable was stroke, measured by the history of medical diagnosis of stroke (at least one episode of stroke, diagnosed by a doctor, at any time in the past). The corresponding asked terms were "stroke", "cerebrovascular accident", "brain haemorrhage", and "cerebral ischemic". This is a validated measure and may be used in epidemiological studies, with an estimated sensitivity of 80% and specificity of 99%²³. Yet, the positive predictive value among individuals older than 60 years is greater than those younger than 60 years (83% and 73%, respectively)²³. The main determinants in this study were difficulty in taking medications. We included self-reported difficulty in taking

medications, an IADL derived from the modified version of the Lawton IADL scale²⁴, and difficulty affording prescribed medications. The difficulty affording prescribed medications was assessed by the question: "Do you skip any prescribed medication due to difficulty affording it?" (yes/no).

Other determinants of stroke were classified according to groups of social-demographic characteristics, health status and the number of medications. Social demographic characteristics included age, complete years of education, and living arrangements. Living arrangements were classified according to the family member living at the same house. It was divided into living alone, living with a partner and other arrangements (i.e. other relatives, such as grandchildren and siblings, and people out of the family, such as friends). Health status included the number of comorbidities, the medical diagnosis of depression, MMSE score, measured body mass index (BMI) and disability. The number of comorbidities was measured by self-reported medical diagnosis of chronic diseases, including diabetes, cancer, arthritis, lung disease, and osteoporosis. MMSE score was dichotomized into with and without cognitive impairment, considering the validated cut-off set for the Brazilian population across education categories (20 for illiterates and 24 other education levels)²⁵. Disability was assessed by self-reported limitations in IADL in six activities: preparing a meal, shopping for groceries, making telephone calls, doing work around the house, managing money, and taking public transport or cab²⁶. We excluded from IADL the activity "taking medication" in order to avoid collinearity. Disability was defined as having any limitation in one or more activities.

Statistical methods

Descriptive analysis was based on Rao-Scott chi-square test whether the variables were categorical and based on t-test whether the variables were continuous. We implemented Logistic Regression to estimate the odds ratio (OR) and their 95% confidence intervals to set the association between stroke and difficulty in taking medication. Multivariate analysis was performed adding groups of determinants as follows: (1) adjusting by social-demographic characteristics; (2) adjusting by health-related characteristics; (3) adjusting by the number of medications.

Additionally, we stratified the association between difficulty in taking medication and stroke by living arrangements to visualize how this rela-

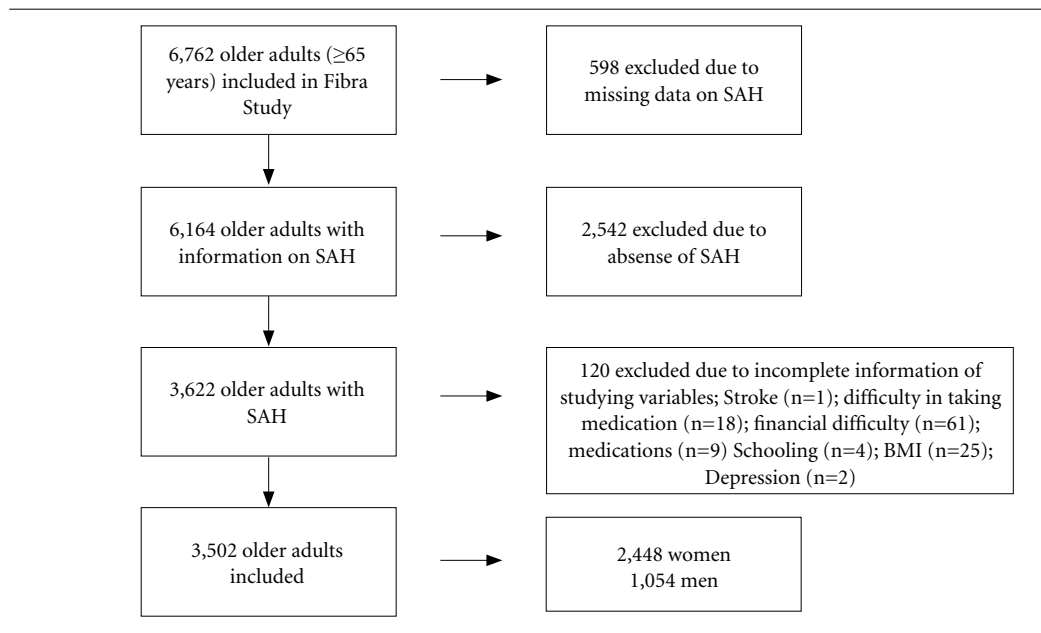


Figure 1. Flow diagram of sample selection. Systemic arterial hypertension (SAH) and difficulty in taking medication – Frailty in Brazilian Older People (Fibra) Study (2008-2009).

Source: Authors' elaboration.

tionship varies according to living arrangement categories. All analyses were performed using STATA 13.0 (Stata Corp LLP, College Station, TX), considering the sampling parameters (individual weight and household clustering of individuals), and conducted separately for men and women.

Results

The descriptive analysis by stroke is presented in Table 1. Most of the older adults were women (70%), mean age 73.1 years (SD = 6.1 years). The prevalence of stroke was 8.6% (not including sampling parameters), self-reported by 302 participants. Difficulty in taking medication was reported by 8.5% of participants and difficulty affording prescribed medication by 24.7%. Only age, living arrangement, BMI and cognitive impairment were not associated with stroke in the univariate analysis ($p < 0.05$).

Table 2 shows the results of the multivariate analyses of the association between stroke and difficulty in taking medication for men and women. Among men, we observed a positive association between self-reported difficulty in taking medication and stroke (OR = 1.96; 95%

CI: 1.13, 3.39) but not for difficulty affording prescribed medication (OR = 0.86; 95% CI: 0.51, 1.43). On the other hand, considering women, neither difficulty in taking medication nor difficulty affording prescribed medication was statistically significant (OR = 1.52; 95% CI: 0.95, 2.42 and OR = 1.35; 95% CI: 0.97, 1.88, respectively).

Additionally, we stratified difficulty in taking medication according to living arrangements and fitted another multivariate model to test possible modification. The results were shown in Table 3. We can see that men with difficulty in taking medication and living with a partner have higher odds (OR = 4.31; 95% CI: 1.43, 12.96) of having stroke compared to those without difficulty in taking medication and living alone. This pattern was not observed among women (OR = 1.13; 95% CI: 0.39, 3.25).

Based on these results, the predicted probability of having stroke among men and women was plotted in Graph 1.

Discussion

This study found that older men with SAH, which report difficulty in taking medication by themselves (unintentional non-adherence), have higher

Table 1. Descriptive analysis of the participants with systemic arterial hypertension (SAH) according to stroke status – Frailty in Brazilian Older People (Fibra) Study (2008-2009).

Variables	Total	Stroke		P value
		No	Yes	
Sex, (%)				<0.001
Male	30.0	29.2	39.4	
Female	70.0	70.8	60.6	
Age, mean (SD)	73.1 (6.1)	73.0 (6.1)	73.7 (6.2)	0.084
Years of education, mean (SD)	4.3 (4.2)	4.4 (4.2)	3.9 (3.8)	0.039
Living arrangement (%)				0.292
Living alone	14.2	14.4	11.9	
Living with a partner	32.1	31.8	35.4	
Other living arrangements	53.7	53.8	52.6	
Body mass index, mean (SD)	27.8 (5.1)	27.9 (5.1)	27.7 (5.2)	0.591
Number of medical diagnosis of chronic diseases, mean (SD)	1.3 (1.1)	1.2 (1.1)	1.6 (1.2)	< 0.001
Medical diagnosis of depression (%)	20.5	19.9	27.2	0.003
Cognitive impairment ^b (%)	30.7	30.2	35.6	0.051
IADL Disability ^c (%)	42.2	40.2	63.3	< 0.001
Number of medications, mean (SD)	3.2 (2.3)	3.1 (2.3)	3.7 (2.6)	< 0.001
Difficulty in taking medications (%)	8.5	7.5	18.5	< 0.001
Difficulty affording prescribed medications (%)	24.7	24.1	30.5	0.015
Total	3,502	3,200	302	

Note: estimated percentages, considering the sampling parameters; SD: standard deviation; ^a including diabetes mellitus, angina or heart attack, cancer, arthritis, lung disease, osteoporosis; ^b measured by mini-mental state examination score, cutoff of 20 for illiterates and 24 other education levels; ^c IADL: instrumental activities of daily living (preparing a meal, shopping for groceries, making telephone calls, doing work around the house, managing money and taking public transport or cab).

Source: Authors' elaboration.

Table 2. Multivariate logistic regression analyses of factors associated with stroke in 3,502 older adults with systemic arterial hypertension (SAH) by sex – Frailty in Brazilian Older People (Fibra) Study, Brazil (2008-2009).

Variables	Men		Women	
	OR	95% CI	OR	95% CI
Age	1.00	0.96; 1.03	0.99	0.97; 1.02
Years of education	1.03	0.99; 1.08	0.91	0.91; 0.99*
Living arrangement (<i>versus</i> living alone)				
Living with a partner	2.06	0.90; 4.73	0.82	0.49; 1.39
Other living arrangements	1.20	0.51; 2.84	1.05	0.68; 1.63
Body mass index	0.93	0.89; 0.98*	1.01	0.98; 1.04
Number of medical diagnosis of chronic diseases	1.11	0.90; 1.37	1.32	1.15; 1.52**
Medical diagnosis of depression	1.17	0.68; 1.99	1.34	0.95; 1.88
Cognitive impairment	1.43	0.90; 2.26	0.92	0.66; 1.29
IADL disability ^a	2.29	1.47; 3.55**	2.27	1.59; 3.22**
Number of medications	1.08	0.99; 1.16	1.05	0.99; 1.12
Difficulty in taking medication	1.96	1.13; 3.39*	1.52	0.95; 2.42
Difficulty affording prescribed medication	0.86	0.51; 1.43	1.35	0.97; 1.88

95% CI: 95% confidence intervals; OR: odds ratio, adjusted by all variables listed in the table; ^aIADL: instrumental activities of daily living (preparing a meal, shopping for groceries, making telephone calls, doing work around the house, managing money, and taking public transport or cab); * p < 0.05; ** p < 0.001.

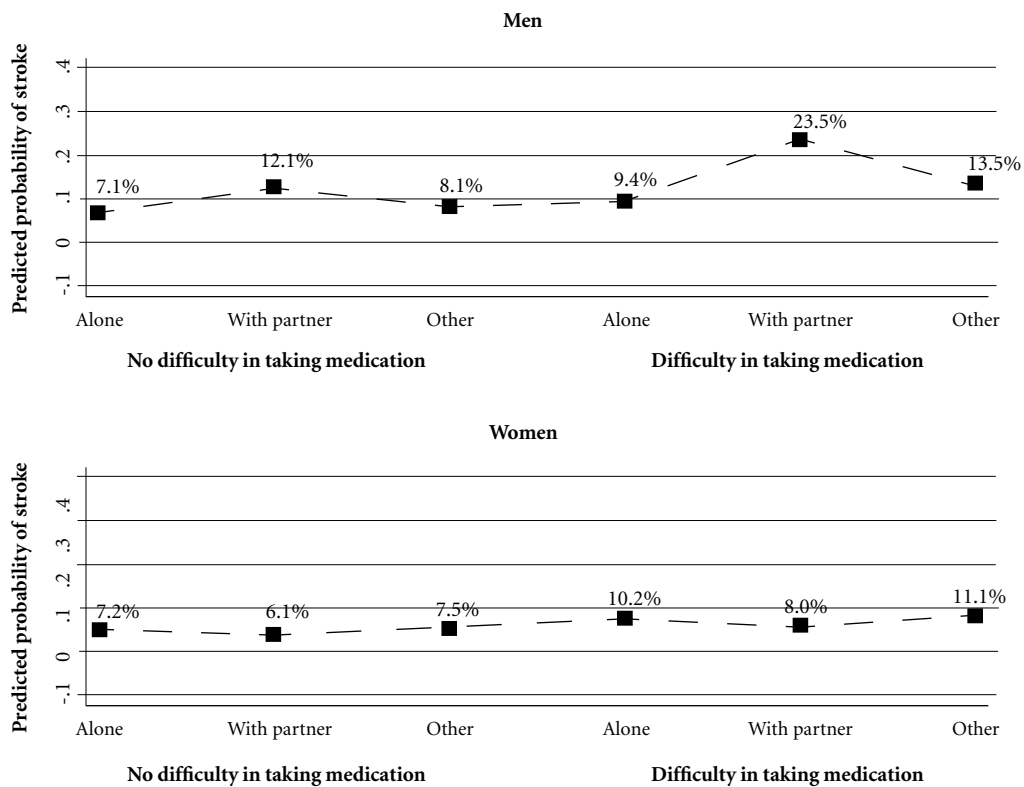
Source: Authors' elaboration.

Table 3. Stratified association of difficulty in taking medication and living arrangements with stroke among older men and women with systemic arterial hypertension – Frailty in Brazilian Older People (Fibra) Study (2008-2009).

Variables	Men			Women		
	Prevalence	Stroke		Prevalence	Stroke	
		OR ^a	95% CI		OR ^a	95% CI
No difficulty and living alone	7.1	1.00		7.2	1.00	
No difficulty and living with a partner	12.5	1.92	0.79; 4.66	6.1	0.83	0.48; 1.44
No difficulty and other living arrangements	8.1	1.17	0.46; 2.98	7.5	1.04	0.66; 1.65
Difficulty in taking medication and living alone	9.3	1.37	0.13; 14.19	10.2	1.48	0.39; 5.64
Difficulty in taking medication and living with a partner	23.5	4.31	1.43; 12.96*	8.0	1.13	0.39; 3.25
Difficulty in taking medication and other living arrangements	13.5	2.10	0.73; 6.07	11.1	1.64	0.85; 3.16

95% CI: 95% confidence intervals; OR: odds ratio; ^a adjusted by age, education, body mass index, number of comorbidities, depression, cognitive impairment, instrumental activities of daily living disability, number of medications, and financial difficulty affording prescribed medications; ** p < 0.001.

Source: Authors' elaboration.



Graph 1. Predicted probability of having stroke among men and women according to difficulty in taking medication and living arrangement – Frailty in Brazilian Older People (Fibra) Study (2008-2009).

Source: Authors' elaboration.

odds of stroke, but not women. Antihypertensive medications are one of the main therapies⁷ to control BP and avoid stroke. Surprisingly, when we stratified by living arrangements, those who have been living with a partner showed higher odds of stroke compared to those without difficulty in taking medication and living alone. We expected that living with a partner or other living arrangements might lead to adequate support availability and consequently higher treatment adherence. Indeed, our results should be interpreted carefully, considering our sample prevalence of difficulty in taking medication (8.5%), quite low compared to Brazilian National Health Survey data (31.8%)¹⁹. This variance could be attributable to our set cut-off of the MMSE at 17. Older adults with IADL disability have a lower MMSE score compared to those without (13.2 *versus* 16.9 among Brazilian men, respectively)²⁷. Therefore, we have been considering only people who are potentially independent but for some other reasons rather than cognitive impairment report difficulty in taking medication. This hypothesis was tested excluding those classified as having cognitive impairment according to the education level. After these exclusions, the association between wedded men who reported difficulty in taking medication and stroke remained significant (OR = 5.44; 95% CI: 1.42, 20.85) (data not shown).

Despite relatively high levels of access and treatment among older people with SAH³, including physician visits and medication supply, hypertension control was fairly low in Brazil²⁸. Brazil has instituted a government program that provides lower-priced medications, named "Popular Pharmacy Program" (Farmácia Popular do Brasil) since 2004²⁹. Recently, most Brazilians with Hypertension have full access to medication (97.9%), most available for free with a prescription via SUS (56%) or lower-priced in drugstores accredited (16%)³⁰. Thus, as showed in our results, difficulty affording prescribed medication in Brazil is not relevant for BP control and avoiding SAH complications. Data from Brazilian older adults (≥ 50 years) under antihypertensive drug treatment has shown a BP under control prevalence of 51.1%³¹, whereas considering only elderlies (≥ 65 years) with hypertension, BP under control prevalence decreases to 31.7%¹⁷. Some of the greatest barriers for achieving BP control are the lack of medication adherence^{10,11} (adequate and regular intake), due to both intentional and unintentional. Our findings support that unintentional non-adherence plays a role in stroke. For instance, a cohort study from Korea

found that poor adherence (i.e. medication possession ratio less than 50%) to antihypertensive drugs increased the risk of cerebrovascular disease by 27% compared with those that showed higher adherence⁹.

Although BP control is low in both sex²⁸, and consequently higher risk of stroke, we found that difficulty in taking medication (unintentional non-adherence) is significant only among men. Unintentional non-adherence is a passive process whereby patients fail to adhere to prescribing medication through forgetfulness, carelessness, or circumstances out of their control, which forgetfulness is the most common¹⁸. This process is not random and reported to be associated with sex, in the sense that women have 9% lower odds¹⁸. Accordingly, previous studies have found that men were twice more likely than women to underutilize healthcare services, such as a general medical consultation or BP screening³². Women have been more proactive in accessing and using health services, providing greater opportunities to early treatment and preventive health education activities for controlling it in primary care settings³, including lifestyle changes and medication intake. In our study, despite women have a statistically higher prevalence of SAH (63.5% in women *versus* 54.9% in men), the prevalence of stroke was statistically high among men than women, 11.3% and 7.5%, respectively, showing that men have more complications (data not shown). Part of these might be attributable to the greater proportion of women with SAH using medication when they are under a drug treatment (95.2%) compared to men (93.4%, $p = 0.026$)³⁰. On the other hand, lower education determines drug underutilization in both sex³². In the current study, this pattern was found among women, which showed decreasing odds of stroke for schooling (OR = 0.91; 95% CI: 0.91, 0.99).

Those data of poor hypertension control due to unintentional non-adherence reinforce the hypothesis that BP control is not an easy task. It often requires a life-long treatment that needs patients high compliant. Literature reports that routine use of home BP assessment improves antihypertensive medication adherence and BP control^{10,33}. Therefore, it is highly recommended along with other feedback techniques, such as pill boxes³³ and standardized measures³⁴. Home visits are another way of reinforcing educational information about treatment for patients and caregivers and promote motivational interviewing³³. Wide breadth of strategies, such as those made by nurse practitioners, is routinely recommended³⁵.

Yet, it is important to state that those strategies are more effective among women and high-income patients³³.

Strikingly, when we stratified men with SAH by living arrangement, we found a higher odds of having stroke among those men who have difficulty in taking medication and living with a partner (OR = 4.31; 95% CI: 1.43, 12.96) compared to those without difficulty in taking medication and living alone. Therefore, those strategies should not be focus only on patients but targeting non-paid caregivers as well. Some caregivers are themselves disabled, suffer from cognitive impairment or have lower education. In the case of a male stroke survivor who has a partner caregiver, the spouse may, for instance, withhold medication from the patient, give them a lower dose than recommended, forget to refill the prescription, or do not give the patient their medication at the right time³⁶. Considering patients who have suffered a stroke, these behaviors may be strengthened by difficulty in taking medication arising from hemiplegia, visual field defects, unilateral neglect, and dysphagia³⁶.

The current study has some positive and negative points. The primary positive point is the methodology using a community-based selected sample derived from fourteen municipalities from different regions of Brazil. This ensures its external validity to Brazilian community-dwelling older adults to guide policy-making. However, we should consider the cross-sectional design, which does not allow us to set a causal chain be-

tween difficulty in taking medication and stroke. Thus, longitudinal study designs are needed to supply this gap. Furthermore, due to the unavailability of objective measures of BP control, it was not measured directly. Therefore, we cannot discard that informational bias (misclassification) may occur because of self-reportness, attenuating the estimated parameters. Although through the community-based sample we can estimate the impact of non-intentional medication adherence on stroke and reinforce primary care actions on medication adherence. Other pathways might explain the relationship between difficulty in taking medication and stroke rather than BP control, but our results are reasonable throughout literature. Yet, considering the large community-based population sample, important clinical measures of cardiac conditions that might influence in stroke were not available for adjustment. And we did not include lifestyle changes, such as salt intake or consumption of meat with visible fat, reported to be higher among male adults in Brazil³⁷, which might influence pro and con BP control and its complications.

Considering men, unintentional difficulty in taking medication plays a role in SAH treatment to avoid adverse outcomes such as stroke. This pattern is especially important when the older adult is living with a partner, with increases, even more, the adverse outcomes. Therefore, primary care strategies for controlling blood pressure should not be focus only on patients, but targeting spouses as well.

Collaborators

JL Torres contributed to idea and design; JL Torres, AL Neri, E Ferrioli and RA Lourenço contributed to acquisition of data, analysis and interpretation of findings; writing – original draft: JL Torres and LP Lustosa; writing – review and editing: JL Torres, AL Neri, E Ferrioli, RA Lourenço and LP Lustosa.

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