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Brazilians' perception regarding the use of generic drugs for hypertension and their equivalence relationship to reference drugs

Percepção de brasileiros quanto ao uso de medicamentos genéricos anti-hipertensivos e sua relação de equivalência aos medicamentos de referência

Percepción de los brasileños sobre el uso de medicamentos antihipertensivos genéricos y su relación de equivalencia con medicamentos de referencia

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Abstract
To identify the degree of knowledge about the use of generic drugs of the antihypertensive class in two Brazilian municipalities and to correlate the sociodemographic profile and its comparison with the reference use. Observational research of descriptive and quantitative nature of participants who used generic Antihypertensive drugs. Data collection was done through an online questionnaire on Google Forms. The sociodemographic profile was (69.0%) female and (31%) male. The average age presented was 34. (62.0%) from the city of Santarém/PA, while (38.0%) from the city of Dourados/MS. Different professional categories, such as: Nurses, Pharmacists, Administrators and Physiotherapists added up (64.0%) to the prevalence of generic drug use. The average salary ranged from 3 to 5 thousand reais. When obtaining the medication (63.0%) obtained it without a prescription. (56.0%) receive information about the drug they would use, the quality of the drug and the need for use, but (44.0%) of the population left the consultation without proper information. (63.0%) of the research participants said the advertisement associated with the use of generics is not positive. As for non-adherence to the use of generic drugs, (50.0%) of the participants had no reason not to use the medication, while (12.0%) would only not use it due to commercial unavailability. The participants' perception of the use of generic drugs in relation to reference drugs is positive, the population showed a good level of knowledge, identifying generic drugs and accepting them.
Keywords: Generic drugs; Hypertension; Pharmacotherapy.

Resumo
Identificar o grau de conhecimento sobre o uso de medicamentos genéricos da classe anti-hipertensivos em dois municípios brasileiros e correlacionar o perfil sociodemográfico e seu comparativo ao uso de referência. Pesquisa observacional de natureza descritiva e quantitativa de participantes que fizeram uso de medicamentos genéricos anti-hipertensivos. A coleta dos dados foi feita através de um questionário online no Google Forms. O perfil sociodemográfico foi de (69,0%) do gênero feminino e 31% do gênero masculino. A idade média apresentada foi de 34 anos. (62,0%) da cidade de Santarém/PA, enquanto (38,0%), da cidade de Dourados/MS. Diferentes categorias profissionais, como: Enfermeiros, Farmacêuticos, Administrador e Fisioterapeutas somaram (64,0%) da prevalência do uso de medicamentos genéricos. A média de salários foi de 3 a 5 mil reais. Na obtenção da medicação (63,0%) obtiveram sem receita médica. (56,0%) recebem informações sobre o medicamento que iriam fazer uso, a qualidade do fármaco e, a necessidade quanto ao uso, mas (44,0%) da população saí da consulta sem a informação devida. (63,0%) dos participantes da pesquisa a propaganda associada ao uso de genéricos não é positiva. Quanto à não adesão ao uso dos medicamentos genéricos, (50,0%) dos participantes não possuíam motivos para não usar a medicação, enquanto (12,0%) só não usariam devido à indisponibilidade comercial. A percepção dos participantes ao uso de medicamentos genéricos em relação aos fármacos de referência é positiva, a população apresentou ter bom nível de conhecimento, identificando os medicamentos genéricos e, aceitando.
Palavras-chave: Medicamentos genéricos; Hipertensão; Farmacoterapia.

Resumen
Identificar el nivel de conocimiento sobre el uso de antihipertensivos genéricos en dos municípios brasileños y correlacionar el perfil sociodemográfico y su comparación con el uso de referencia. Investigación observacional de carácter descriptivo y cuantitativo con participantes que utilizaron medicamentos antihipertensivos genéricos. La recolección de datos se realizó a través de un cuestionario en línea en Google Forms. El perfil sociodemográfico fue (69,0%) femenino y 31% masculino. La edad promedio presentada fue de 34 años. (62,0%) de la ciudad de Santarém/PA, mientras que (38,0%) de la ciudad de Dourados/MS. Las diferentes categorías profesionales, como: Enfermeros, Farmacéuticos, Administradores y Fisioterapeutas explicaron (64,0%) de la prevalencia del uso de medicamentos genéricos. El salario medio era de 3 a 5 mil reales. Al obtener medicamentos (63,0%) los obtuvieron sin receta. (56,0%) reciben información sobre el medicamento que iban a utilizar, la calidad del fármaco y la necesidad de su uso, pero (44,0%) de la población salió de la consulta sin la información necesaria. (63,0%) de los participantes de la investigación, la publicidad asociada al uso de genéricos no es positiva. En cuanto a la falta de adherencia al uso de medicamentos genéricos, (50,0%) de los participantes no tenía motivo para no utilizar el medicamento, mientras que (12,0%) sólo no lo utilizaría por indisponibilidad comercial. La percepción de los participantes sobre el uso de medicamentos genéricos en relación a los medicamentos de referencia es positiva, la población mostró un buen nivel de conocimiento, identificando medicamentos genéricos y aceptándolos.
Palabras clave: Medicamentos genéricos; Hipertensión; Farmacoterapia.

1. Introduction

During the implementation process of the Brazil's unified health system (Sistema Único de Saúde - SUS), in the early 1990s, the formulation of a policy for generic drugs in Brazil was initiated by Law 9.787 of 1999, considered a milestone for public health (Arrais et al., 2005). At the beginning of the implementation of policies related to generics, there was resistance to replacing these drugs on the market, however, over the years this scenario has changed due to the advantages arising from cost-effectiveness, guarantee of interchangeability and proof of bioequivalence and bioavailability being a purchase alternative to the Brazilian population or free supply by the health system (Villamañán et al., 2016). Since their commercialization, generics have shown a significant reduction in prices, which in general is 30%, which can be extended to 50% and have the same safety as the same quality as the reference medicine (Bertoldi et al., 2016).

The process of epidemiological and sociodemographic transition in recent years has contributed to changes in national epidemiological patterns, as they have determined a profile of chronic diseases including arterial hypertension (Oliveira et al., 2023). According to data from the World Health Organization (WHO), it is estimated that 1.28 million adults, between 40 and 79 years of age, have some form of the disease, with only 42% being diagnosed and treated and of these 21% have hypertension controlled (Brettler et al., 2022; Kim et al., 2019).

Treatment includes lifestyle changes and/or pharmacological treatment to maintain blood pressure levels within reference values (Silva et al., 2022). Although there are several existing therapeutic options available on the market, blood pressure control is not that simple, there are countless factors for non-compliance by the patient, data that corroborate the study carried out in Santa Catarina with hypertensive patients in a unit basic health showed low adherence to the use of generic antihypertensive drugs, due to distrust of the quality and efficacy of the drug and consequently affecting its treatment (Smith et al., 2015).

This scenario is consistent with the reality of many patients who usually form a conception based on false news and prior knowledge about the perception that well-known branded drugs are superior to generic drugs and express concern about their effect despite scientific evidence demonstrating the opposite (Tian et al., 2020), mainly due to the price disparity between the drugs based on the belief that the cheap one has a worse quality (Shrank et al., 2009).

Studies show that the average cost of medicines in some countries is high, in Brazil it is no different, generics are a therapeutic alternative that has conquered the market on an exponential scale with great speed, showing the ability to meet requirements based fundamentally on the amounts involved and guarantees of safety profiles and quality of the product made available and, being thus thought of in its character of the treatment of Pharmacotherapy, an important issue when we base

ourselves on the therapeutic alternatives that are available to improve the quality of life of the population (Júnior et al., 2021).

The decrease in prices is since generics are produced by other laboratories at the end of the patent and the exclusive right of the laboratory that researched and developed the medicine is lost (Montrucchio et al., 2003). As a result, today generic and similar drugs are an alternative to purchase and supply free of charge by the Unified Health System, this alternative is based on quality assurance and a reduced price when compared to original medications (Lima et al., 2020). A class of drugs that deserves special attention is that of antihypertensives, as in addition to being used by approximately 20% of the Brazilian population, there are now more than 191 generic and similar drugs on the market used in the treatment of arterial hypertension with selected active ingredients for this work, most of them available in the Popular Pharmacy program (Anvisa, 2014). Considering that these drugs are used continuously, mainly by older individuals, where the prevalence of arterial hypertension is extremely high, determining their interchangeability is extremely important from the point of view of pharmacovigilance (Silva, 2022).

The Ministry of Health, through the Secretariat of Health Policies, in partnership with CONASS and CONASEMS, outlined complementary strategies to the process of acquisition and availability of these medicines considered essential by the WHO and present in the National List of Essential Medicines – RENAME (Costa et al., 2020) in Brazil to treatment of hypertension, hydrochlorothiazide 25 mg, captopril 25 mg and propranolol 40 mg were considered as first-line drugs. The last revision of RENAME, in 2008, included Losartan potassium in the class of antihypertensive agents that are angiotensin receptor antagonists (Costa et al., 2020).

When it comes to the private market, most drugs are available in the generic option, however, there is still resistance within the population regarding the purchase of drugs from this class, therefore, it is important to carry out studies on the adherence of generic drugs in the country so that the factors associated with the mystification of this drug can be known.

In view of this, it is questioned whether there is a difference between the knowledge of the population in different municipalities in Brazil regarding the use of generic drugs of the antihypertensive class.

Our objective with this work is to identify the level of knowledge about the use of generic antihypertensive drugs in two Brazilian municipalities and correlate the sociodemographic profile and its comparison with the reference use.

2. Methodology

This is a descriptive and observational study with a quantitative approach, whose research field was the cities of Santarém, a municipality located in the northern region of the State of Pará and Dourados, Mato Grosso do Sul, Brazil. The data was collected using the Google Forms tool carried out from June 1st to July 1st. An instrument was developed and used to collect data containing the following variables: age, sex, occupation, place of birth and family income. The identification of the social structure implies discovering the social differences of the participating members and understanding the lived universe from an internal perspective, from the point of view of individuals and the situations in which they live (Gil et al., 2017).

The initial sample target population consisted of twenty patients using antihypertensive drugs, excluding four patients. The research was approved by the Comitê de Ética da Invitare Pesquisa Clínica, opinion number (CAAE n. 69030323.5.0000.8098) and all participants signed the informed consent form (TCLE) based on resolution 466/2012 of the Conselho Nacional de Saúde.

Several techniques are adopted to collect data in action research. The most common is the collective or individual interview. The questionnaire is also used, especially when the universe to be researched is made up of a large number of elements (Gil et al., 2017). In this work, the data were double entered, organized and processed through descriptive statistics in Excel spreadsheets (Microsoft Office® 2016) taking into account the variables contained in the collection instrument.

3. Results and Discussion

3.1 Results

In all, from June 1 to July 1, 2023, a total of twenty individuals participated in the study. Of these, four were excluded, as they did not fit the research inclusion criteria. The data presented in (Table 1) demonstrate the sociodemographic characteristics of the 16 study participants. There was a significant predominance of participants' gender, ranging from 20 to 60 years old (mainly people at the age of 34). Regarding the profession variable, different professional categories make or have made use of generic drugs, Nurses, Pharmacists, Administrators and Physiotherapists totaled (64.0%), we also observed that more than half of the participants (62.0%) are residents of the city of Santarém, State of Pará with monthly income with a prevalence of three to five minimum wages.

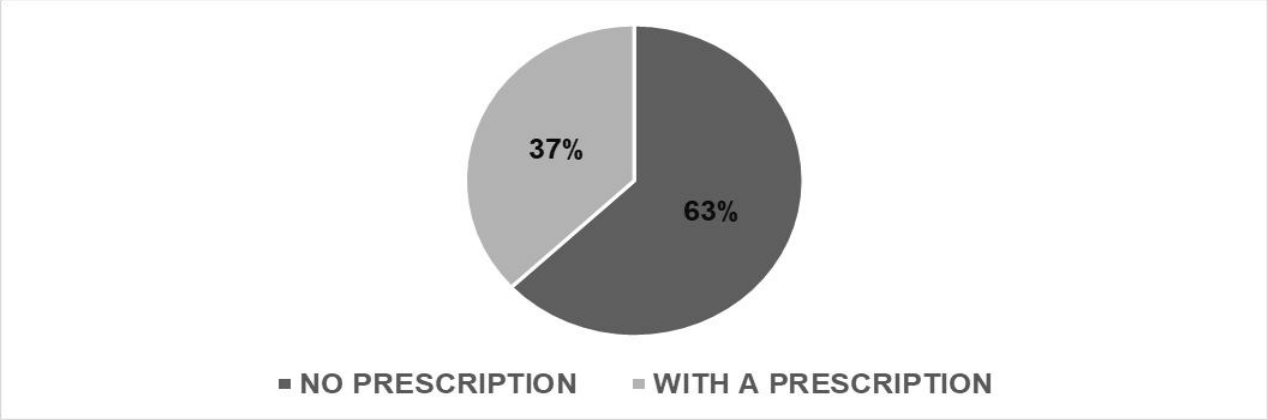
Table 1 – Distribution of variables according to sociodemographic characteristics in the cities of Santarém/PA and Dourados/MS, Brazil, 2023.

Sociodemographic characteristics	Sample (n=16)	%
Gender		
Women	11	69%
Men	5	31%
Age		
20 to 30 years old	5	25%
31 to 40 years old	7	35%
41 to 50 years old	3	15%
65 to 75 years old	4	20%
Over 60 years old	1	5%
Occupation / Job		
Nurse	4	25%
Pharmacist	2	13%
Administrator	2	13%
Physiotherapist	2	13%
Production Operator	1	6%
Public employee	1	6%
Teacher	1	6%
Driver	1	6%
Retired	1	6%
Student	1	6%
Location		
Santarém/Pará (PA)	10	62%
Dourados/Mato Grosso do Sul (MS)	6	38%
Monthly Wage Income		
01 to 02 wages	6	37%
03 to 05 wages	7	44%
Over 05 wages	3	19%

Source: Authors.

Regarding obtaining medication, about 63% (10 people) obtained the medication without a prescription (Figure 1).

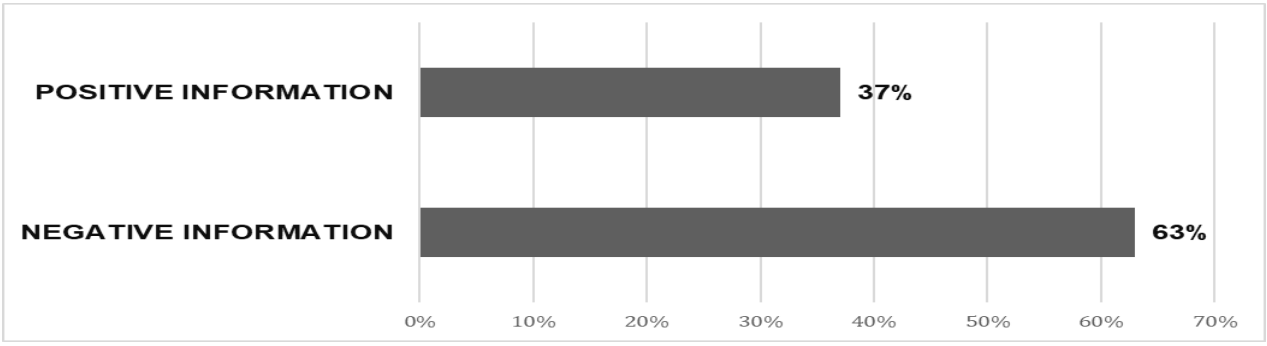
Figure 1 - Obtaining Medicines without Prescription of participants in the cities of Santarém/PA and Dourados/MS, Brazil.



Source: Authors.

When analyzing data on the use of generic drugs among the participants and obtaining information in a medical consultation to purchase the medication, we noticed that 56% (n=9) receive information about the drug they would use, the quality of the drug and, the need for use. On the other hand, we observed that 44% of the population (n= 7 participants) left the appointment without proper information. An expressive and significant data of results (Figure 2).

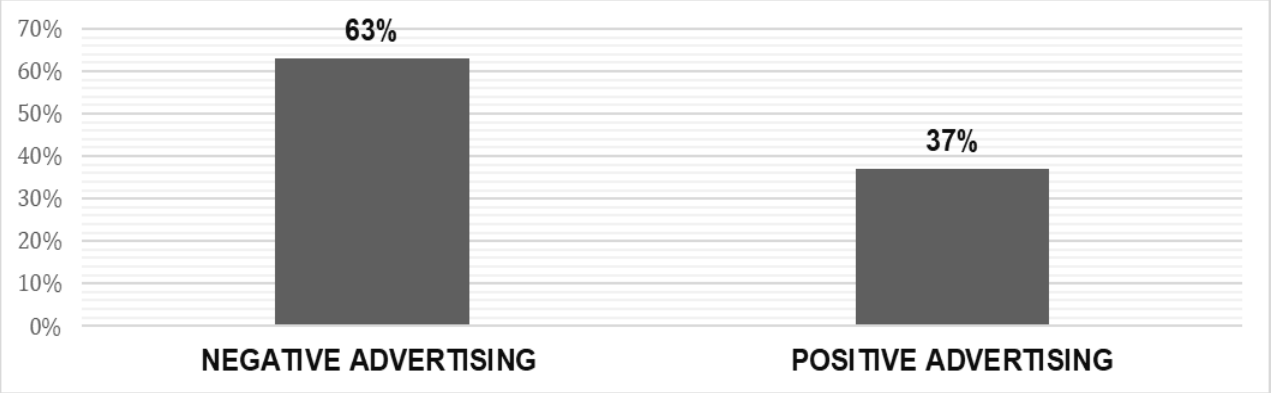
Figure 2 - Information on the use of Generic Medicines by participants in the cities of Santarém/PA and Dourados/MS, Brazil.



Source: Authors.

Regarding the criteria for disclosing information related to the use and use of generics in Brazil, we observed a negative data in the study. For 63% of the research participants (n= 10) it demonstrates that the advertisement associated with the use of generics is not positive (Figure 3).

Figure 3 - Disclosure of the use of Generics in Brazil by participants in the cities of Santarém/PA and Dourados/MS, Brazil.



Source: Authors.

As for non-adherence to the use of generic drugs, we observed that 50% of the participants (n = 8) had no reason not to use the medication, while 12% (n = 2) would only not use it due to commercial unavailability (Table 2).

Table 2 - Description of the causes of non-adherence of participants regarding the use of generic drugs in the cities of Santarém/PA and Dourados/MS, Brazil.

Why wouldn't you use a generic drug?	**Total**	**% Total**
No reason not to use	8	50,00
Commercial unavailability	2	12,00
High cost	2	13,00
Contraindication	1	6,00
Distrust of drug quality	1	6,00
Did not answer	2	13,00
Total number of participants	**16**	**100**

Source: Authors.

3.2 Discussion

Information on the use of generic antihypertensive drugs comparing two Brazilian states is scarce and outdated in current literature. The data obtained in this study summarize the use of generic drugs among two populations with completely different local and cultural characteristics.

The sociodemographic profile of the participants in this study is mostly represented by females (n=11). Data that corroborate the study by Jesus and collaborators who presented similar results (Jesus et al., 2008).

The average age was 34 years old, with participants ranging from 21 to 63 years old. Age averages per age group per period were represented as 20 to 30 years old - 5 participants - with an average of (24.4 years). For the group of 31 to 40 years old - the largest group of participants, with 7 in total - the mean age was (35 years old). In the 41 to 50 age group - 3 participants - the average was 43 years old.

We had no participants in the group represented between 51 and 60 years old. For the group aged 61 to 70 years we had 1 representative participant. Data that differ from the study by Borelli and collaborators when describing the sociodemographic profile showed that it affects 60% of the population aged over 60 years as they are factors associated with chronic noncommunicable diseases (NCDs) (Dos Santos et al., 2022).

When analyzing "Income and Medicines Procurement, we find that, according to Ordinance No. 3.916/GM the profile of the Brazilian consumer is made up of three classes: the first represents 15% of the population, has an income above 10

wages – minimum and consume 48% of the total drug market; the second is formed by 34% of the population's income, has around 4 to 10 minimum-conflicts and consumes 36% of the market and the third is repaired by 51% of the population with income from zero to 4 do-minimums and consumes only 16% of the market (Política Nacional de Medicamentos, 2000). This fact demonstrates that for socioeconomic reasons, access to medicines does not occur equally in the population, being compromised for millions of Brazilians who have low income.

The constant increase in the prices of medicines on the market is one of the factors that end up driving the population to the public service (Costa et al.,2020). We noticed through our data from the regions in the study that the socioeconomic profile of the participants is from three to five minimum wages, the average salary was five thousand reais, being higher than the national average when compared. The locations where this study was developed are strategic cities in the Brazilian economy and the study participants had a higher education background.

In the analysis of obtaining medication without a prescription, about 63% (10 people) obtained the medication without a prescription. These data are in line with the information released by the Ministry of Health in Brazil, which mentions the relationship of self-medication as a worrying and public health factor. This is in line with other studies conducted in developed countries (Blatt et al., 2012) and developing countries which show that the habit of self-medication is associated with the presence of minor signs and symptoms of acute characteristics (headache and fever, for example) as being signs and symptoms that stimulate the use of over-the-counter medicines, as well as geographical location and access difficulties, are factors that influence the use of self-medication (Smith et al., 2015; Arrais et al., 2015).

The use of marketing and advertising language, with its mythologies, places in the general consciousness of society that well-conceived branded products are products of higher quality and greater affectivity. In a certain way, a myth is created that the product without a brand or a brand not so well known - the case of generics - has less efficiency and effectiveness. Several international governments, including Brazil, have advocated the replacement of branded drugs by their generic versions to control rising health costs. One of the existing studies investigating nine cardiovascular drugs found that generics had equivalent clinical action to branded drugs (Freitas et al., 2014), (Júnior, et al., 2021). All drugs called generics undergo tests to prove bioequivalence and bioavailability in relation to the branded drug. Therefore, the generic drug is no better and no worse. A generic drug must be bioequivalent and bioavailable in relation to the branded drug, that is, from the moment the person takes the pill, the time of action between one and the other must be the same, the amount released of the drug in the body as well, and may vary shape and color of the tablet, for example.

Regarding participants' non-adherence to the use of generic medicines, we observed that 50% (n = 8) did not present reasons for not using the medicine, thus, our study is in line with the statistical data found from research participants, in practice, Generic and similar medicines are analogous to reference medicines, differing in the fact that generics use the name of the active ingredient and similar medicines use the commercial name. With the emergence of generic medicines, it has always been mandatory to present bioquivalence tests, whereas for similar medicines the obligation began in 2003 (Anvisa, 2014). Factors of resistance to their use have already been described despite the important advantages of generic medicines, which can be described as: (1) scarce access to these products in pharmacies (Blatt et al., 2012); (2) scarce prescription by medical professionals (Anvisa, 2014; Silva et., 2015); (3) low knowledge of health professionals (García et al., 2003); (4) lack of guidance for use (Vallès et al., 2002); and (5) absence or no knowledge, associated with consumers' negative beliefs regarding its use.

4. Conclusion

When describing the sociodemographic and economic profile of the population studied, it was possible to observe that the female gender was more prevalent with an average age of 34 years old and salary income between three and five minimum

wages. Regarding the participants' perception of the use of generic drugs in relation to reference drugs, this study demonstrates a positive adherence, the population presented a good level of knowledge, enough to identify generic drugs, and accepts their use well.

This result may be associated with the twenty years of implementation of the generic drug policy by the Ministry of Health, which has contributed greatly to regulating prices and ensuring the efficacy and safety of drugs, to maintain and/or increase the confidence of the population and health professionals in the use of medicines. However, advertising actions are still needed to stimulate the spread of knowledge about such products, whether in health establishments, through prescribers, since there is still a portion of the population that does not yet know or use generics, regardless of the level of education and age group, which contributes to mistaken opinions that underestimate the quality of the product and cause its low use, since it was noted that the greater the knowledge about generics, the greater the preference for their use.

We hope that this article contributes to the transparency of policies and uses of generic medicines, highlighting their use and all the actions taken to date. Our idea is to encourage future studies for other regions, enabling the development and improvement of targeted policies focused on demystifying their use, as there are still some questions about their effectiveness. Stimulating the search for a health professional, such as a pharmacist, can be an effective proposal, reducing the risks of misuse and increasing its popularization and demystification of biases that may still cause obstacles.

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