



Artículo Original | Original Article

Use of industrialized herbal medicines by patients attended at the basic health units in the County of Pinhais, Paraná, Brazil

[Uso de medicamentos fitoterápicos industrializados por pacientes atendidos en unidades básicas de salud en el municipio de Pinhais, Paraná, Brasil]

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Abstract: The present article studied the use of industrialized phytotherapies by patients attended at the basic health units in Pinhais county, located in the metropolitan region of Curitiba, Paraná, Brazil. This is a quantitative, observational and cross-sectional study that was conducted by semi-structured questionnaire interviews that were used as a data collection instrument. The population sample consisted of 267 patients from basic health care organizations. Regardless of gender or age, 56.2% of the interviewed participants reported using industrialized herbal medicines, of which 21.3% acquired their drugs from drugstores from around the county. Patients reported positive results using industrialized herbal medicines (89.33%), of whom women were predominant, making up (80%) ($p < 0.05$). Among the drugs used by all the patients, “guaco” syrup was the most frequent (34%). The present study demonstrates the good acceptance by patients of treatments that involve integrative practices, such as herbal medicine, but when a drug has a vegetal origin, the idea that these products do not cause adverse effects persists.

Keywords: Herbal medicine, Basic health care, Integrative practices

Resumen: El presente artículo se estudió el uso de hierbas medicinales procesadas por pacientes tratados en unidades básicas de salud del municipio de Pinhais, en la región metropolitana de Curitiba, Paraná, Brasil. Se trata de un estudio cuantitativo, observacional y transversal, realizado por medio de entrevistas que utilizan como instrumento de recolección de datos un cuestionario semi-estructurado. La población de la muestra consistió en 267 pacientes de atención básica a la salud. Independiente del sexo o de la edad, 56.2% de los entrevistados relató hacer uso de fitoterápicos industrializados, siendo que de los 21.3% hizo la adquisición en las farmacias de las unidades de salud del municipio. Los pacientes reportaron resultados positivos con el tratamiento realizado con fitoterápicos industrializados (89.33%). Entre ellos predominan las mujeres (80%) ($p < 0.05$). Entre los medicamentos citados por los pacientes, el jarabe de guaco se mostró el más frecuente (34%). El presente estudio demuestra la buena aceptación por parte de los pacientes en realizar tratamientos que implican prácticas integrativas como la fitoterapia, pero, por poseer origen vegetal, todavía existe la idea de que estos productos no tienen la capacidad de causar efectos adversos.

Palabras clave: Fitoterápico, unidades básicas de salud, prácticas integrativas

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INTRODUCTION

The use of herbal medicines and medicinal plants in disease treatment is one of the oldest therapeutic practices of the humanity and has been used for centuries. This knowledge was built over the years with the contribution of popular knowledge and scientific experience (Ferreira *et al.*, 2014).

In ancient Egypt (1,500 BC) at approximately 1873, the use of plants with therapeutic purposes in the Ebers' Papers was demonstrated, stating the use of phytotherapy by Egyptians. Approximately 2,500 BC, there were evident advances in Traditional Chinese Medicine and the first records of the widespread use of medicinal plants were observed (Herbarium, 2012).

The evident benefits of plants were corroborated by the identification of the Egyptian documents dating to 3,000 BC, which had already emphasized the use of natural products, such as opium by Sumerians and Babylonians (Herbarium, 2012).

The use of herbal medicines as a therapeutic resource was officially recognized by the World Health Organization (WHO) in 1978 (Brasil, 2001), reaffirming the aid of phytotherapies and medicinal plants in the maintenance and recovery of health (Brasil, 2001; Niero *et al.*, 2003; Brasil, 2006a; Brasil, 2008).

Currently, in many countries, most part of the population depends on the use of medicinal plants in health care. However, modern medicine stands side by side with traditional herbal medicine practice in maintaining its use for cultural factors and reasons.

The results published in a systematic review aimed to investigate the prevalence of the complementary use of alternative medicines, including the use of herbal medicines by the general population, which demonstrated the prevalence of use in countries, such as Australia, Canada, Finland, Israel, United Kingdom and the United States (Harris & Rees, 2000).

In general, there is ample use of medicinal plants by the populations of the different origins and regions of the world. Herbal products not registered as drugs in Canada are sold as food and therefore are exempt from the drug review process evaluating the efficacy and safety of the product (Kozyrskyj, 1997). In contrast, in the United States, most herbal products on the supermarket are marketed and regulated as dietetics and supplements, a category of products that

does not require prior approval, being evaluated by reports of adverse effects (Chang, 1999).

In countries such as Germany, herbal medicines are subject to strict manufacturing standards and sold as "phyto-medicines". In addition, they are subject to the same efficacy, safety and quality criteria as for other pharmaceutical products (Keller, 1991). The widespread use of herbal medicine in this country is evident, as approximately 70% of the doctors prescribe it regularly. Germany has a long tradition of the consumption of natural products, which were also registered as traditional use products (Calixto, 2000; Herbarium, 2012).

One of the main challenges for German primary health care in strengthening the use of herbal medicine is related to the promotion of knowledge and skills development in this area (Joos *et al.*, 2012).

In Cuba, the use of medicinal plants by patients treated in primary health care is promoted through the National Health System, which seeks to strengthen the implementation of alternative and complementary practices (Rivas *et al.*, 2002).

Similarly, in Chile in 1992, the Traditional Medicine Unit was created with the objective of incorporating traditional medicine with proven efficacy in health programmes to contribute to the establishment of this practice. Herbal medicinal products are legally differentiated into medicinal products and food products intended to cure, alleviate or prevent disease (Calixto, 2000).

In other countries, such as Argentina, the distribution of some herbal medicines by the Medicinal Specialty Laboratory of the Ministry of Public Health of the Misiones province provides more than one treatment alternative for patients (Falkowski *et al.*, 2008).

The French Agency for Medicines (Agence du Médicament) grants marketing authorizations for herbal medicine based on abbreviated dossiers, which refer to traditional use. Traditional uses were first published in 1985 by the Ministry of Health and subsequently revised several times (AESGP, 1998). Since 1997, the French Pharmacopoeia had a list of local medicinal plants (Castot, 1997), which grouped 454 herbs whose benefit/risk ratio is considered positive when traditionally used.

Medicinal plants are distributed in several countries worldwide; however, they are more abundant in tropical countries, such as Brazil, which have approximately 22% of the world's biodiversity

at approximately 55 thousand plant species, presenting great potential for growth in the economic sector (Brasil, 2001).

In Brazil, the strengthening and growth of implanting phytotherapy in the Unified Health System (SUS) was more evident after the 1980s, where several Resolutions, Portaries and Reports were elaborated focusing on the availability of phytotherapeutic drugs in basic health units (Brasil, 2001).

By the year 2006, through the Decree of the Presidency of the Republic No. 5.813, dated June 22, the National Policy of Medicinal Plants and Phytotherapeutics was created (Brasil, 2006a). In the same year, in cooperation with this programme, the insertion of phytotherapies in the SUS was carried out through Ministry of Health Decree No. 971 of May 3, 2006, which approved the National Policy on Integrative and Complementary Practices in SUS, which are the guidelines for the implementation of Medicinal Plants and Phytotherapy (Brasil, 2006b).

The herbal medicines were redefined by Resolution No 26 on May 13, 2014, in which they are defined as technically elaborated, industrialized products, which originated as vegetal raw materials that were characterized by of their effectiveness and efficiency, proved by clinical evidence, related risks to its use, reproducibility and maintenance of its quality (Brasil, 2012; Brasil, 2014).

Correspondingly, the National Sanitary Surveillance Agency also defines a traditional phytotherapeutic product, the safety and effectiveness of which can be proved by the means of data published in the technical-scientific literature, and there is no need for clinical evidence (Brasil, 2014).

Thus, when the term "industrialized herbal medicine" is used here, the terms "phytotherapeutic medicines" and "traditional phytotherapeutic products" are included, according to RDC No. 26 of May 13, 2014.

In this sense, this study performed an analysis about the use of industrialized herbal medicines by patients attended at basic health organizations of Pinhais county, located in the metropolitan region of Curitiba, Paraná, Brazil.

MATERIALS AND METHODS

This is a quantitative, observational and cross-sectional study.

Pinhais county has a total population

estimated at 117,998 habitants according to the Brazilian Institute of Geography and Statistics (2010), being the fifth city in the number of inhabitants of the counties that compose the metropolitan region of Curitiba, which is composed of 29 municipalities. The county has 10 Family's Health organizations, which are: Ana Neri, Esplanade, Maria Antonieta, Perdizes, Perneta, Tarumã, Tebas, Vargem Grande, Vila Amelia and Weissópolis.

For the sample definition, a probabilistic study was chosen, with a random stratified sampling proportional, a margin of error of 6% and a confidence level of 95%. For the sample calculations, the number of visits performed by each basic health organization in 2014 was taken into account.

The primary patient data collection was obtained by semi-structured interviews, during February and March 2016, in all the county health organizations according to the sample calculation.

The sample was composed of a total of 267 patients, who signed a Term of Free and Informed Consent after invitations and clarifications about the research objectives.

The data collection instrument was previously evaluated through a pilot study involving 10 patients from health organizations in Pinhais, which were not used to compose the final sample. This step was performed to check if the developed research instrument would be viable. For it is through the effective application of the questionnaire that one can verify flaws that can pass unnoticed by the researcher (Barbetta, 2011).

The final script of the semi-structured interview covered the following topics: experiences using industrialized herbal medicines; ways of acquiring industrialized herbal medicine; improvement after the use of herbal medicine; and general characteristics, such as gender, age and schooling. In a complementary manner, the patient was asked if he or she used medicinal plants without medical indication.

The interviews were randomly carried out by the researcher at the basic health organizations preceding physician attendance at the time of the withdrawal of medication in the pharmacy.

The interviews had free time, with no refusal rate. Data regarding the interviews were analysed with the help of the Statistica 7.0 program. For the analysis of the association of the variables, a chi-

square test was used.

The study was authorized by the Municipal Health Department of Pinhais and approved by the Ethics Committee of the Federal University of Paraná

- Health Sciences Sector, on December 11, 2015, under opinion 1,363,771 and CAAE 49439615.0.0000.0102.

TABLE 1

Description of the characteristics of interviewed patients using industrialized phytotherapies

Characteristics of patients	f	%
MAKES PHYTOTERAPIC		
Yes	150	56,2
No	117	43,8
SEX		
Male	30	20
Female	120	80
AGE		
18-29	31	20,6
30-49	51	34
50-69	58	38,6
70 or more	10	6,66
SCHOOLING		
Elementary School		
Incomplete	45	16,8
Complete	28	10,4
High school		
Incomplete	75	28
Complete	82	30,7
Higher education	29	10,8
Did not know how to report	8	3

(f) Frequency.

SOURCE: The author (2016).

RESULTS AND DISCUSSION

The population sample was composed of 267 patients interviewed in the health units of Pinhais county, including individuals over 18 years of age, of which 80% were female and 20% were male, with different levels of schooling.

The most prevalent age group was between 50 and 69 years old (38.6%) compared to the ages of the patients interviewed with the use of herbal medicines, no significant statistical result was observed ($p>0.05$) (Table No 1).

Independent of gender or age, 56.2% of the

individuals interviewed were reported to have used industrialized herbal medicines when necessary.

When questioned about the place where they obtained these medicines, 21.3% reported that they were obtained in the pharmacies of the county health units studied. Countries, such as Cuba and Argentina, similarly seek to promote the use of medicinal plants by patients receiving primary health care, providing some options through the National Health System (Rivas *et al.*, 2002) and Laboratory of Medicinal Specialties of the Ministry of Public Health of the Missões province of, providing one more alternative

treatment for patients (Falkowski, 2008).

When we evaluated the schooling of patients using phytotherapeutics, it was observed that 30.7% of patients finished high school and 10.4% of patients who finished elementary school. No statistically significant relationship was observed between using phytotherapeutics and the schooling of the interviewees ($p > 0.05$) (Table No 1).

This result differs from a similar study (Silva, 2003), carried out with patients using phytotherapy at the Basic Units of Family Health Care of Maracanaú, Ceará, in which it was observed that the majority of patients interviewed had only attended elementary school (75.7%).

It is noted that the insertion of the phytotherapeutics in the routine consultations carried out in basic health care is still limited. Of the patients interviewed, only 20.2% had undergone medical consultations in which the professional indicated an industrialized herbal medicine to perform the therapy. This reinforces the lack of medical participation in the prescription of these drugs. In this case, the presence of self-medication could be observed, since 56.2% of the individuals interviewed reported using industrialized herbal medicines when necessary.

According to data from the World Health Organization (WHO), a large part of the population in developing countries uses traditional medicine to treat health problems, with 80% using traditional practices. Among these practices, 85% of the users used medicinal plants or their preparations to treat health problems, which makes traditional medicine complementary to basic health needs and basic health care (BRASIL, 2006a).

At least one-third of American adults use some form of alternative therapy annually. In a study of patients with neurological diseases, 40% of the patients were reported to use at least one alternative therapy for the treatment of Parkinson's disease (Rajendran, 2001).

In some countries such as Iraq, the preference for using natural products can also be observed by the medical team, which chooses to prescribe natural products. This fact was demonstrated in the city of Hawler (Iraq) where part of the medical team interviewed (47%) patients and opted to use herbal medicines for urological treatment (Mutalib, 2015).

The sale of medicinal plants in countries such as Germany is quite expressive, approximately 600-700 plants are sold, contributing to the expansion of its use. In addition, 70% of physicians prescribe herbal medicines, where part of the annual sales are paid for by government health insurance (Blumenthal, 1988; Herbarium, 2012).

In a complementary manner, in Germany, phytotherapy is known as one of the five main elements of classical naturopathy, showing an increase of users over the years and the percentage of German herbalists increased from 52% in 1970 to 70% in 2010 (Joos et al., 2012).

In the scope of the SUS, public policies, such as the National Policy of Medicinal Plants and Phytotherapeutics and the National Policy of Integrative and Complementary Practices in the SUS, reinforce the need and importance of valuing traditional knowledge, to stimulate research in the field of alternative medicine and contribute to rational use in the field of herbal medicine. In this way, the participation of health professionals who can contribute to the expansion and application of these policies is of fundamental importance, allowing the inclusion of phytotherapy in public health services in Brazil.

Pinhais county has 3 herbal medicines in its Municipal Relation of Essential Medicines (REMUME), including guaco syrup (*Mikania glomerata* Spreng.), holy thorn capsules (*Maytenus officinalis* Mabb.) and soy isoflavone capsules (*Glycine max* (L.) Merr.).

In general, 89.3% of patients who reported the use of herbal medicines stated improvement after the treatment, characterizing this therapy as an effective alternative. Other studies have shown that there is acceptance of the use of herbal medicines by primary health care patients (Silva, 2003; Tomazzoni et al., 2006; Oliveira et al., 2012).

When asked about the need to stop treatment because they did not achieve the desired improvement, 83.3% said that there was no need to replace the herbal medicine with other treatment alternatives. Some patients reported more benefits when using herbal medicines, citing relevant advantages when compared to other products and synthetic drugs (Table No 2).

Table No 2
Advantages cited by patients using phytotherapy

Reasons claimed by patients for use of herbal medicines	Frequency	%
"It has no chemistry: it is "natural "	73	48.6
"It is same as a common medicine (synthetic medicine)"	30	20
"Less aggressive to the organism"	30	20
"It takes time to work, but it has a good result"	7	4.6
"Cheaper"	2	1.3

SOURCE: The author (2016).

The fact that these industrialized herbal medicines originated from plants facilitates their acceptance because they are associated with a natural origin and supposedly safe and without contraindications, meaning that they do not contain "chemicals". However, although the population generally believes that herbal medicines have no side effects, cause less dependence and are less aggressive, studies confirm that plants have toxic constituents that can cause health risks (Calixto, 2001; Gomes *et al.*, 2005).

Tomazzoni *et al.* (2006) similarly observed that the preference for medicinal plant use is related to the patients' belief and association that plants have healing properties, are more reliable, effective and have fewer side effects than other synthetic medicines.

Corroborating this point, the interviewed patients at the University Hospital of Heidelberg, Germany, reported that the use of herbal medicine is better because it has more satisfactory effects and fewer side effects compared to conventional medicine (Joos *et al.*, 2012).

Similarly, in a national survey conducted in Italy, 15.6% of the patients interviewed in the Italian population reported having used non-conventional therapy, citing phytotherapy (4.8%). The main reason for such use was concern about the potential toxicity of "conventional medicine" (Menniti-Ippolito *et al.*, 2002).

Following the same line, some patients believe that the chemistry of the synthetic products can be harmful to the organism, promoting more side

effects, rather than contributing to the improvement of a certain pathology (Teixeira & Lefèvre, 2001).

However, it is known that there is a group of plants that have a toxic capacity and their use has been classified as insecure (Klepser & Klepser, 1999).

Of the 43.8% of the patients who did not use herbal products, 96.6% favoured their use when necessary, and 3.4% would not accept phytotherapy as an alternative treatment. Some justifications for non-adherence to phytotherapeutic use has been reported as a "delay in working" or that "it does not work".

All interviewees cited an example of industrialized herbal medicine, which they had already used or were using (Table No 3).

It is possible to observe the predominance of guaco syrup utilization by the interviewed patients (34%). Its therapeutic use is due to popular knowledge associated with scientific knowledge (Alcantara *et al.*, 2015), which proves and indicates its action as an expectorant and bronchodilator, among other indications, provided by the presence of chemical compounds, such as coumarins (Cavallazzi, 2006; Amaral *et al.*, 2009; Brasil, 2001; Rename, 2015). This may contribute to the fact that this is the medicine noted by the interviewed patients.

In Germany, the therapeutic use of herbal medicines is common, with several indications, including respiratory tract infections, cardiovascular diseases and gastrointestinal symptoms (Calixto, 2000; Joos *et al.*, 2012).

Table No 3
Industrialized phytotherapies cited by interviewed patients

Name	Pharmaceutical form	Frequency	%
Arnica (<i>Arnica montana</i> L.)	Ointment	2	1.3
Indian chestnut (<i>Aesculus hippocastanum</i> L.)	Capsules	11	7.3
Espinheira Santa (<i>Maytenus officinalis</i> Mabb.)	Capsules	11	7.3
Figatil® (<i>Cynara scolymus</i> L., <i>Peumus boldus</i> Molina)	Syrup	1	0.6
Garra do Diabo (<i>Harpagophytum procumbens</i> DC. ex Meissn. and <i>Harpagophytum zeyheri</i> Decne)	Capsules	5	3.3
Ginkgo (<i>Ginkgo biloba</i> L.)	Capsules	9	6.0
Guaco (<i>Mikania glomerata</i> Spreng.)	Syrup	51	34
<i>Hedera helix</i> L.	Syrup	5	3.3
Soy Isoflavone (<i>Glycine max</i> (L.) Merr.)	Capsules	17	11.3
Passiflora (<i>Passiflora incarnata</i> L.)	Capsules / Syrup	17	11.3
Sominex® (<i>Valeriana officinalis</i> L., <i>Passiflora incarnata</i> L., <i>Crataegus oxyacantha</i> L.)	Capsules	7	4.6
<i>Tribulus terrestris</i> L.	Capsules	4	2.6
Valerian (<i>Valeriana officinalis</i> L.)	Capsules	10	6.6

SOURCE: The author (2016)

The most common condition for people in the United States that use alternative therapies, such as herbal medicine, include back problems, anxiety, depression, and headaches (Eisenberg *et al.*, 1998).

When the use of these drugs by the patients interviewed could be observed, the consumption of products did not agree with the municipality studied. Complementarily, it is evident that even those medicines made available by the county are not fully acquired in the health organization, including one of the 34% of patients who use guaco and 14.66% had access to the drug by SUS. Regarding soy isoflavone, of the 11.33% who use it, 4% reported access in the health units of Pinhais. Finally, when evaluating the acquisition of espinheira santa, 2.66% of the 7.33% who use herbal medicines obtained this medicine free in the SUS units.

It is not possible to ignore the fact that self-medication occurs among patients, which may be influenced by the recommendation of lay people or previous medical prescriptions (Arrais *et al.*, 1997; Vilarino *et al.*, 1998). This may explain, in part, the non-acquisition of all the industrialized herbal medicines in the health units studied, which the county of Pinhais agreed with.

One of the concerns is that the vast majority of patients using medicinal plants without their physician's knowledge, as they are often encouraged by family, friends and the media (Rajendran *et al.*, 2001; Paula *et al.*, 2012).

It is evident the industrialized herbal medicines are predominantly used in the population between 50-69 years of age (38.6%). An increase in the number of users of industrialized plants and herbal products in older age groups has been observed. This was found by Genovés *et al.* (2001), who identified a higher consumption of medicinal plants in groups aged between 45 and 64 years.

This behaviour may be related to the cultural and historical factor that involves the use of herbal medicines in the treatment of several diseases (Leite, 2005), which may favour the use of these products according to an increase in the age group of the studied group. Complementarily, the elderly use health services more frequently, being in a group that is commonly diagnosed with various chronic diseases (Chaimowicz, 1997; Veras, 2009).

By crossing the data obtained in the gender of the patients interviewed with the use of industrialized herbal products, it can be observed that there is a

significant statistical relationship ($p < 0.05$), demonstrating that women use more industrialized herbal products compared to men (Table No 1).

It has been observed in this study that the majority of interviewees who reported using industrialized herbal medicines as well as medicinal plants were female. These characteristics were agree with other studies. Silva (2003) reported the use of herbal medicines in basic health care in the city of Maracanaú-Ceará, where 85.4% of the patients interviewed were female. Studies have shown that there is a greater prevalence of drug use by women in relation to men (Bertoldi *et al.*, 2004; Oliveira *et al.*, 2012; Tavares *et al.*, 2015)

Regarding the user profile, a systematic study realized by Frass *et al.* (2012) assessed the use of complementary and alternative medicine by the interviewees. From the survey conducted, the authors found that women were more prone to use these therapies compared to men.

The results obtained could indicate that the gender of the patients could be considered a determinant factor for the use of industrialized herbal medicines. This may be related with a greater frequency of women seeking medical care and health care because they are more concerned about their health. It may also be related with greater health programme offerings to the female public (Bertoldi *et al.*, 2004).

The lower percentages of herbal medicine use observed in the group of men may be related to cultural situations, which require men to seek less primary health care services, that relate the disease to weakness and insecurity, leading to the devaluation of self-care (Figueiredo, 2005; Gomes *et al.*, 2007) When asked if they used medicinal plants for self-medication, 81.65% of the interviewed patients reported using it when necessary to treat health problems.

The use of medicinal plants is common in other countries, such as Canada, where 546 medicinal plants traditionally used by aboriginal forests in Canada were identified (Uprety *et al.*, 2012).

Great satisfaction with the use of medicinal plants was observed. Paula *et al.* (2012) report that 37% of patients used medicinal plants for oral treatments and that of these were satisfied with the results reached and that there were no adverse effects during treatment.

FINAL CONSIDERATIONS

In a similar way to that observed in other countries, there was good acceptance of industrialized herbal medicines by the patients to during treatments once these treatments demonstrated efficacy and safety, according to the users interviewed.

The use of phytotherapeutics was more extensive in women than in men, and schooling and age were not statistically relevant regarding the use of herbal medicines. There is a strong cultural factor due to the old belief that "natural" products do not harm health, as demonstrated by the increasing tendency to use medicinal plants.

The patients interviewed received prescriptions for phytotherapeutics, which were different from those made available by the municipality studied. This demonstrates the need to review and expand the list of herbal medicines offered and standardized in the health units of the evaluated county.

In addition, it is important to improve the relationship between the doctor and the patient so that there is a reduction in self-medication, ensuring increased safety and effectiveness in the performed therapy.

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