

## USE OF HERBAL REMEDIES: MEDICAMENTAL EFFICACY AND CHALLENGES FOR THE POPULATION ACCESS THROUGH THE UNIFIED HEALTH SYSTEM (SUS)

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**Abstract:** Phytotherapeutics are drugs whose active principles are extracted from plants. Such medications may have anti-inflammatory, antibacterial and analgesic properties, which are important for the systemic postoperative period. The National Policy on Medicinal Plants and Phytotherapeutics is regulated by Decree No. 5,813, of June 22, 2006, whose general objective is to guarantee the Brazilian population safe access and rational use of medicinal plants and phytotherapeutics, promoting the sustainable use of biodiversity, the development of the production chain and the national industry. In this context, the objective of this work is to demonstrate the importance of phytotherapeutics in the systemic postoperative period, pointing out, as a consequence of this relevance, the legal and regulatory mechanisms that ensure access and dissemination of phytotherapeutic medicines. The methodology used to achieve the objective was bibliographical and documentary, supported by pertinent literature and legislation, through the delimitation of concepts, comparative study of theses and critical analysis of jurisprudence.

**Keywords:** phytotherapy, wound healing, right to health, Unified Health System (SUS).

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### 1. Introduction

It is the State's duty to promote and guarantee the right to health under social and economic, as provided for in art. 196 of the Constitution of the Federative Republic of

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Brazil in 1988. Understanding access to health as a constitutional precept, the efforts of the public power for its implementation do not end in conventional therapies, such as which are allopathic medicines. The use of phytotherapy in the post-surgical period has been shown to be as another mechanism of public power to enable the full exercise of the right to health, emerging as the objective of the present study.

The right to health is included in the integrated set of actions initiated by public powers and society. As a consequence of the constitutional provisions concerning the aforementioned right, state actions aimed at promoting health, including the inspection and control of procedures, products and substances, as well as allopathic and herbal medicines.

In view of the above, understanding herbal medicines as viable solutions for the expansion of the provision of health care by the State, the question is: state policies provided for in the governing legislation are effective in ensuring broad access by the population to this alternative therapy?

## **2. Approach to oral surgical procedures**

Surgical procedures result in significant trauma to oral tissues, presenting, as a consequence, the installation of a transient picture of local inflammation and are therefore generally accompanied by pain.

It is currently accepted that bacteremia after invasive procedures, such as extraction dental, may occur in 100% of cases, with their frequency increasing as a result of some factors such as the presence of an inflammatory process, the patient's age, time of duration of surgery and volume of blood lost during these procedures (BARROS *et al.*, 2000).

The widespread use of medicinal plants and their different therapeutic actions warn that the use of these pharmacological agents may present benefits in relation to allopathic medicines, especially in developing countries (CORDEIRO *et al.*, 2006).

The isolated use of medicinal plants such as: *Schinus terebentifolius*, *Raddi*; *Piptadenia culverin*, *Benth*; *Physalis angulata*, *Linné* and *Cereus peruvianus* have shown consistent scientific evidence regarding analgesic, anti-inflammatory and antibacterial effects. In

However, the therapeutic action of the associated use of such plants needs to be proven, especially in Dentistry (WANDERLEY *et al.*, 2005).

Surgeries are procedures that are usually accompanied by pain and edema such as direct or indirect consequences of the procedure (BAMGBOSE *et al.*, 2005). According to Bodnar (2001), the inflammatory process is a natural and even desirable consequence of surgical procedures. Therefore, the clinical symptoms manifested pertinent to inflammation are: tumor, redness, heat, pain, and loss of function.

Through a literature review based on clinical evidence, Ong & Seymour (2003) reported that postoperative pain is a common condition in approximately 40% of patients who undergo tooth extractions. In this context, it is important to highlight the distinction between the result of a normal inflammatory process and when it becomes a change that requires some intervention.

In general terms, for Aytés & Escoda (2004), most cases of tooth extraction are considered a simple intervention, which if carried out carefully and competently only produces mild discomfort and leads to rapid healing, and should not be inflammatory process extends beyond five days.

According to Oliveira *et al.* (2007), Brazil has great potential for the development of Phytotherapy applied even to Dentistry, as it presents the greatest plant diversity in the world, with the use of medicinal plants linked to traditional knowledge and technology to scientifically validate this knowledge.

In recent decades, the use of herbal medicines by the population has taken a new direction, based on experimental research that proves its effectiveness. Substances such as: aroeira, angico, camapu, mandacaru, malva, *aloe vera* and purple top, have proven to be efficient in reduction of the inflammatory process.

Lucena *et al.* (2005) evaluated the efficacy of the hydroalcoholic extract of the aroeira tree through an experimental study with 40 male *Wistar rats*. The rats were divided randomly into two groups of 20: Aroeira group (GA) and Control group (GC), which in turn were subdivided into subgroups of 10 animals (SGA/ SGC). In the animals of the group control, after cystorrhaphy, a single dose of saline solution was injected into the peritoneal cavity 0.9% in the proportion of 1 mL/kg; in the GA group, the hydroalcoholic extract of the aroeira was injected at a concentration of 100mg/kg, with the dose calculated as 100mg/kg. After the procedure, the wound was cleaned with Povidine®. In the postoperative period, the wound conditions surgical procedures were evaluated daily and possible complications were noted. The criteria evaluated were: macroscopically: signs of infection, adhesions and the site of cystorrhaphy;

microscopically: acute inflammation, chronic inflammation, ischemic necrosis, reaction giant cell type foreign body, reepithelialization, coaptation of suture edges, extension of the wall infiltrate, capillary neoformation, fibroblastic proliferation and fibrosis. After analysis statistics of histological parameters on the 3rd and 7th postoperative day, it was concluded that the use of the hydroalcoholic extract of aroeira showed a favorable healing effect in cystotomies in rats.

Regarding studies in the dental field, Lisboa Neto *et al.* (1998), seeking to evaluate the effect healing agent of the mastic tree (*Schinus terebenthifolius*) and the mastruço (*Chenopodium ambrosioides*) in dental extraction wounds, carried out a study with 30 rats of the lineage *Wistar*, which were divided into three groups of ten animals: group I (control); group II (aroeira); group III (mastruço). The animals underwent extraction of the upper incisor right and in sequence, the test substances were injected into the alveoli; then the alveoli were sutured with silk thread. The authors concluded that in the first five days there was significant difference in repair (inflammatory infiltrate), comparing the control and experimental. In 15 days of observation, differences were noted between the aroeira and the mastruço, which suggested that the first substance showed antiseptic or healing effects better than the second, because in this phase granulation tissue predominated in the group mastruço and in the control group.

Poor *et al.* (2002) evaluated the incidence of postoperative alveolitis after treatment of patients with clindamycin gel or SaliCept® (*Aloe Vera*) in the form of a patch on the post-surgical alveoli. 1194 patients were evaluated, divided into two groups, which were operated on by the same surgeon. The results showed that the incidence of postoperative alveolitis in the group treated with clindamycin gel was 8%; while the SaliCept® treated group was 1.1%. Therefore, the SaliCept® patch significantly reduces the incidence of postoperative alveolitis when compared to the use of the gel of clindamycin.

In order to evaluate the therapeutic effects of *Schinus terebenthifolius*, Raddi in tissue repair process on ulcerated lesions of the oral mucosa of rats, Ribbas MO *et al.* (2006), used 60 male *Wistar rats*. 25 rats were part of the group experimental group and 35 in the control group. Ulcerated lesions in the oral cavity were induced chemically through daily topical application of 40% sodium hydroxide to the mucosa that covers the back of the tongue in its most anterior portion of each animal. Once the lesion is found ulcerated (clinically), it was treated with topical application of leaf extract *Schinus terebenthifolius*, Raddi. The authors demonstrated that the aforementioned phytotherapeutic

accelerated the tissue repair process, stimulating keratinization and acting in the repair of connective tissue, rapidly reducing the intensity of the chronic inflammatory process.

Phytotherapy can potentially provide alternatives for post-operative treatment in medical-dental area. In this sense, scientific studies are needed to legitimize the therapeutic indication of such drugs supported by state policies that enable the its diffusion.

### **3. National Policy on Medicinal Plants and Phytotherapeutics**

Integrative and complementary health practices can be understood as ways alternative treatments for illnesses, disease prevention and health promotion, admittedly less costly for the user. Their interventions seek to contemplate the being human in its entirety, expanding the individual's vision of their own health and providing autonomy in care. Phytotherapy is among the modalities of these practices, as a therapeutic resource.

The National Policy for Integrative and Complementary Practices in the SUS (PNPIC) finds normative basis in Ordinance No. 971, of May 3, 2016. Specifically concerning to phytotherapy, the aforementioned regulation considers, among the clauses justifying its approval, the therapeutic resource from the perspective of different pharmaceutical forms, encouraging community development, solidarity and social participation.

The approach to phytotherapy in the SUS also finds support in the National Policy of Medicinal Plants and Phytotherapeutics, approved by Decree No. 5,813, June 22, 2006, whose guidelines, formalized through the National Program of Medicinal Plants and Phytotherapeutics, were established by Interministerial Ordinance No. 2,960, of December 9 2008.

The National Program of Medicinal Plants and Phytotherapeutics proposes, among others, the insertion of medicinal plants, herbal medicines and services related to Phytotherapy in the SUS, with safety, efficiency and quality, in line with the guidelines of the National Policy of Integrative and Complementary Practices in the SUS, as well as the promotion and recognition of popular and traditional practices of using medicinal plants and home remedies.

According to the Ministry of Health, the SUS offers the population, with resources from of the Union, States and Municipalities, 12 herbal medicines, which are listed in the List

National System of Essential Medicines (RENAME), highlighting the still limited scope of this type of therapeutic resource.

The inclusion of medicinal plants and phytotherapeutics in the list of medicines of the "Pharmacy Popular" also constitutes an action for the development of the guideline "Guarantee and promote the safety, efficacy and quality in access to medicinal plants and phytotherapeutics", indicated, respectively, in items 9.2 and 9 of the annex to Decree No. 5,813/2006.

The use of herbal medicines represents the appreciation of national culture, in addition to recognition of traditional popular knowledge, enabling the preservation of biodiversity. Its inclusion among the integrative and complementary practices of the SUS, it represents a therapeutic option for low cost, also providing integration of human beings with the environment.

Despite the normative provisions regarding the National Policy on Medicinal Plants and Phytotherapeutics, challenges are identified for the implementation and universal reach of herbal medicines, in which the right of access to health is, in fact, exercised as provided for in the Constitution.

#### **4. Legal merit in the distribution of medicines by the State**

The right to health is included in the integrated set of actions initiated by the authorities public and society, making up social security, as set out in art. 194 et seq. of the Federal Constitution of 1988. The topic is addressed in art. 196 of the Magna Carta, inferring if the constitutional provision regarding the State's duty to promote and guarantee the right to health under social and economic aspects:

Art. 196. Health is a right of all and a duty of the State, guaranteed through social and economic policies that aim to reduce the risks of disease and other harm and universal and equal access to actions and services for its promotion, protection and recovery.

In this regard, among the attributions of the SUS we highlight the control and inspection of procedures, products and substances of interest to health, as well as the production of medicines, as provided for in art. 200, I, of the CF/88.

It is also important to highlight the inclusion in the list of SUS attributions, the competence of increase, in its area of activity, scientific and technological development and innovation, provided for in art. 200, V, CF/88, as amended by constitutional amendment no. 85 of 26 February 2015. This makes the public interest in promoting research explicit.

in the health area, adding the vernacular “innovation” to the aforementioned paragraph, point specific that brings us closer to the questions that include the development of studies that contemplate phytotherapeutics, weighing up, in addition to their effectiveness in post-treatment, operational, the reduction of costs. Let's see:

Art. 200. The unified health system is responsible, in addition to other attributions, under the terms of the law: I - to control and monitor procedures, products and substances of interest to health and participate in the production of medicines, equipment, immunobiologicals, blood products and other supplies; (...)

V - increase, in its area of activity, scientific and technological development and innovation;

Notwithstanding the constitutional provision regarding the increase in research to promote health, access to herbal medicines is not yet popularized, lacking more records in the subtle list of the National Health Surveillance Agency (ANVISA), which is not relates to the questioning of its effectiveness, but with economic obstacles that reveal the absence of the State in an assertive manner, demonstrating the real interest in invest in studies that raise herbal medicines to the level of relevance and popularity of allopathic medicines.

Regarding the State's duty to supply and distribute medicines, it is important to highlight that, in a recent decision, the Supreme Federal Court vetoed the possibility of distribution by through state agencies of medicines whose registration has not been carried out in the ANVISA.

The same decision also contemplated the possible exception to the judicial order in the case of delay. unreasonable delay of ANVISA in assessing the request (term longer than that provided for in Law 13,411/2016), and only when three requirements are met: (i) the existence of a request for registration of the medicine in Brazil (except in the case of orphan drugs for rare diseases and ultra-rare);(ii) the existence of registration of the drug with renowned regulatory agencies abroad; and (iii) the lack of a therapeutic substitute registered in Brazil. The actions that demand the supply of medicines without registration with Anvisa must necessarily be proposed to the Union.

In this way, the essential nature of drug registration is demonstrated for provision by the public authorities, enabling the popularization of access, including to herbal medicines. Without research there is no registration. Without resources there is no research. Without registration, there is no provision that does not lead to the “judicialization of health”. It is worth highlighting that public policies aimed at the inclusion in the national health system of effective medicines, with prices accessible to the majority of the population, enforces the

great principle of the Federal Constitution of the dignity of the human person. On another point, the concentrated power in ANVISA's decisions regarding the distribution of medicines, It brings about a real administrative imbroglio, as it intensifies the dispute with another state body called the National Institute of Industrial Patents (INPI), responsible for granting patents in Brazil. In other words, an obstacle was created for the registration of patents for medicines by a competent body and with functions specified by law, in order to have the ANVISA has the final and exclusive power to endorse the substance sold. Finally, the commercialization of herbal medicines, according to scientific research demonstrated in this publication, should be encouraged through public policies that facilitate the preparation and distribution of the aforementioned drugs, thus fulfilling the guarantee constitutional right to access health care.

## **5. Final Considerations**

In general terms, the aim of this article was to ratify the effectiveness of medicines phytotherapeutics as a therapeutic resource in drug treatment, with emphasis on post-operative in Dentistry, demonstrate that state policies for the dissemination of this therapy are still embryonic and incipient, given the limited list of medicines ANVISA's herbal medicines compared to the number of allopathic medicines available in market.

In this line of understanding, it is imperative that public policies not only contemplate the scientific research, fundamental instruments for the dispensing of medicines herbal medicines, but actually make possible the popularization of the alternative therapy discussed here. The herbal medicines value traditional folk knowledge about plants with medicinal properties, in addition to contributing to the preservation of the rich biodiversity Brazilian.

It is argued that the expansion of the distribution of herbal medicines is justified not only in view of its proven effectiveness, but, equally, due to the reduction in the cost of treatment costs, specifically in the care provided by the public health network.

It is therefore concluded that the legal provision, without due practical support, only masks the deficiency in health care, a fundamental right provided for in the Constitution.

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