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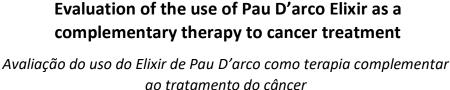
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ABSTRACT

Objective: To evaluate the follow-up of the use of Elixir of Pau D'arco (Handroanthus Avellanedae (Lorentz Ex Griseb) Mattos (Sin: Tabebuia Avellanedae Lorentz Ex Griseb) in complementary therapy for the treatment of neoplasms, produced and dispensed in the Phytotherapy Sector of the Coordination of Pharmaceutical Assistance Policies of the Health Department of the State of Ceará. Methods: This is a basic, descriptive, documentary research based on secondary data with a qualitative and quantitative approach. Results: 387 files were analyzed with clinical records of patients with cancer between the months of March 2016 to March 2020, whose elixir was dispensed with medical prescription (34.5%) and pharmaceutical guidance (65.5%). As for the therapeutic response to treatment, these patients reported a significant improvement with the complementary use of Pau D'Arco Elixir and did not know other integrative practices. Diterpene alkaloids extracted from medicinal plants, such as Taxol, have also been used in the treatment of several types of cancer, among others. Conclusion: These results demonstrate the importance of using alternative complementary medicine in the treatment of neoplasms.

Keywords: Medicinal plants. Neoplasms. Pau d'arco. Purple ipê.

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RESUMO

Objetivo: avaliar o acompanhamento do uso do Elixir de Pau D'arco (Handroanthus Avellanedae (Lorentz Ex Griseb) Mattos (Sin: Tabebuia Avellanedae Lorentz Ex Griseb) na terapia complementar ao tratamento de neoplasias, produzido e dispensado no Setor de Fitoterapia da Coordenadoria de Políticas de Assistência Farmacêuticada Secretaria de Saúde do Estado do Ceará. Métodos: trata-se de uma pesquisa básica, descritiva e documental a partir de dados secundárioscom abordagem quali-quantitativa. Resultados: foram analisadas 387 fichas com cadastros clínicos de pacientes portadores de câncer entre os meses de março de 2016 a março de 2020, cujo Elixir era dispensadocom prescrição médica (34,5%) e orientação farmacêutica (65,5%). Quanto à resposta terapêutica ao tratamento, estes pacientes referirammelhora significativa com o uso complementar do Elixir de Pau D'Arcoe não conheciam outras práticas integrativas. Os alcalóides diterpênicos extraídos de plantas medicinais como o Taxol, também têm sido usados no tratamento de diversos tipos de câncer, entre outros. Conclusão: Estes resultados demonstram a importância do uso da medicina complementar alternativa no tratamento de neoplasias.

Palavras-chave: Plantas Medicinais. Neoplasia. Pau D'arco. Ipê Roxo.

Introduction

Phytotherapy is a medicine that uses medicinal plants to treat diseases, with different applications such as treating diseases, preventing diseases, alleviating disease symptoms or for cosmetic purposes. In Brazil, there are several scientific studies and researches that have contributed to the improvement of phytotherapy. The knowledge of phytotherapy in Brazil is increasingly improving, as modern science has contributed to the understanding of the mechanisms of action of medicinal plants and the effectiveness of their bioactive substances (VIEIRA, 2008).

The World Health Organization (WHO) emphasizes the importance of investing in research on medicinal plants to develop technologies that guarantee the safety of users. Through this investment, it is possible to find and identify the bioactive components of each plant species, as well as establish the ideal concentrations for each herbal medicine. In addition, the WHO recommends that health professionals be educated about medicinal plants so that they can provide accurate information about their use (Vanini, 2011).



The Pau D'arco plant is native to the Amazon and has anti-inflammatory, antibacterial, antifungal, and antiviral properties. Recently, studies have shown that this powerful herbal medicine also has beneficial effects in the treatment of cancer. Studies have shown that the plant has beneficial effects on cancer cells by inhibiting their proliferation, thus preventing their growth and possible spread. In addition, the plant has antioxidant activity, which also contributes to the fight against cancer (Higa, 2007).

Although purple pau d'arco is widely used as an alternative therapy, there are few scientific studies evaluating its efficacy. In vitro and in vivo studies have suggested that purple pau d'arco has anti-inflammatory, antitumor, and antioxidant properties. It has also been shown to have antifungal, antibacterial, and antiviral properties. These studies suggest that purple pau d'arco may be an effective treatment for cancer, but more studies are needed to evaluate its effects on the human body (Oliveira *et al.*, 2014).

In order to contribute to the rational use of herbal medicines as a complementary therapy to oncological treatment, the Phytotherapy Sector of the Coordination of Pharmaceutical Assistance Policies of the Ministry of Health of the State of Ceará (COPAF/SESA), previously called the Phytotherapy Center (NUFITO), started to produce 10% Pau D'Arco elixir as an antitumor and to dispense this herbal medicine in the sector itself, with the patient's clinical record. It is worth mentioning that Pau D'Arco is one of the species included in the State List of Medicinal Plants of Ceará (REPLAME-CE), by Decree No. 275 of March 20, 2012 (Ceará, 2012).

The objective of the study was to evaluate the monitoring of the use of Elixir de Pau D'arco (Handroanthus Avellanedae (Lorentz Ex Griseb) Mattos (Sin: Tabebuia Avellanedae Lorentz Ex Griseb) in complementary therapy for the treatment of neoplasms, produced and dispensed in the Phytotherapy Sector of the Coordination of Pharmaceutical Assistance Policies of the Health Department of the State of Ceará.

1 Method

The study was carried out in the Phytotherapy Sector of the Coordination of Pharmaceutical Assistance Policies of the Health Department of the State of Ceará (COPAF), which consists of the Official Garden (with plants with botanical certification), a primary processing area and a pharmaceutical workshop for the preparation of herbal medicines.



The activities carried out by the Phytotherapy Sector are in accordance with the National Policy on Medicinal Plants and Phytotherapeutics and the Technical Standards of ANVISA, which aim to guarantee the Brazilian population safe access and rational use of medicinal plants and herbal medicines (Ceará, 2009). The Phytotherapy Sector/COPAF is located at Avenida Washington Soares nº 7605, Municipality of Fortaleza, State of Ceará.

It is a basic, descriptive and documentary research, based on secondary data, with a qualitative-quantitative approach.

Regarding its nature, the research is considered basic, as it has the purpose of generating new knowledge beneficial to the advancement of science and includes content of universal interest. In terms of its objectives, the study is descriptive. This type of study observes, records, analyzes, and arranges data without the intervention of the researcher. It seeks to determine the frequency of occurrence of an event, its nature, characteristics, causes, and relationships with other events. It usually takes the form of a survey (Prodanov; Freitas, 2013).

In terms of technical procedures, the research is considered documentary because it uses documents that have not yet been manipulated or that can be reworked according to the objectives of the study. From the point of view of the approach to the problem, the study is qualitative and quantitative because, at the same time as it translates the data into numbers to classify and analyze them, these are not the center of the analysis of the problem under study. The interpretation of phenomena and the attribution of meanings are important in this type of research. The information collected is descriptive, representing as many elements as possible of the reality under study (Prodanov; Freitas, 2013).

The population was composed of data referring to the clinical records of cancer patients who received the Pau D'Arco Elixir for the treatment of different types of cancer, which can confirm the effectiveness of this herbal medicine, identify possible adverse reactions, thus making it possible to obtain safety and efficacy data.

Study data were collected from clinical records between the months of March 2016 and March 2020.



First of all, authorization was requested to collect data and access records related to the topic available at the Phytotherapy Sector/COPAS/SESA. For this purpose, the Depositary Authorization Term with a copy of the project was delivered to the person in charge of the aforementioned sector. After signing the term and the consequent authorization to obtain the data, the research began. To collect the study material, the researcher traveled to the study site, where she gained access to the files and documents.

The documentary research consisted of the following steps: selection of the study topic, definition of the objectives, development of the work strategy (field research), identification and location of the sources to be studied, obtaining and reading the material found, copying and organizing the material into files, spreadsheets and tables for analysis, data interpretation and final writing of the study. These phases were carried out in a natural order (Marconi; Lakatos, 2010).

The data were generated in a database structured in the program Excel-2016 and analyzed in relative and absolute numbers, as well as a descriptive analysis, in the light of the literature: books, scientific articles, theses and dissertations related to the topic.

Institutional authorization was requested from the Phytotherapy Sector/COPAS/SESA to carry out the research, through the Depositary Authorization Term and the Letter of Consent for Conducting Research.

2 Results and discussion

The subject of the study was the analysis of the records of patients with different types of malignant neoplasms who used the Elixir de Pau D'Arco dispensed by the Phytotherapy/COPAF/SESA sector between March 2016 and March 2020.

On-site research was carried out in the aforementioned sector, where the sources to be analyzed consisted of clinical records of patients diagnosed with malignant neoplasms using Elixir de Pau D'Arco (Appendix C). 387 records were analyzed, grouped according to the following neoplasms: Breast (81); Prostate (29); Pancreas (7); Colon (1); Thyroid (4); Stomach (9); Skin (7); Throat (4); Ovary (7); Uterus (6); Lung (15); Ureter (1); Tongue and Lung (1);



Rectum (8); Spine (1); Spleen (1); Myeloma (2); Salivary glands (1); Endometrium, (1); Liver (3); Duodenum (1); Tongue (1); Kidneys, 5; Leg (1); Inguinal lymphoma (1); Gallbladder and liver (1); Thigh (1); Uterus (5); Sarcoma (5); Cervix (5); Sarcoma (3); Bowel (7); Stomach and esophagus (2); Lymphoma (1); Adenocarcinoma (1); Leukemia (2); Gallbladder (2); Bone (3); Esophagus (1); Lung and liver (1); Common bile duct (1); Tongue and lymph nodes (1); Neck (1) (Table 1).

The observed results in the records are consistent with the literature regarding the most prevalent types of cancer in women and men, respectively, breast and prostate cancer (Table 2). According to Cesar *et al.* (2021), based on data provided by the National Cancer Institute (INCA) in 2020, it was estimated that there were 65,840 notifications of prostate neoplasia, representing 29.2%, and 66,280 new cases of female breast cancer, accounting for 29.7% of the total cancers (Cesar *et al.*, 2021).

The registered patients received Elixir de Pau D'Arco in amber 250 mL bottles, with the dosage indicated on the label recommending three tablespoons per day. The quantity dispensed of these bottles varied according to the patient's clinical condition, diagnosis, treatment with other types of medications, and disease progression. Every three months, patients returned to receive nine bottles of this herbal medicine. An estimated production of 50,000 units was recorded over the four-year period from 2016 to 2020.

It was observed that 34.5% of the Elixir de Pau D'Arco used by patients was dispensed with a medical prescription, while 65.5% were dispensed without a medical prescription, i.e., through pharmaceutical guidance with professionals from the Phytotherapy Sector (Figure 1).

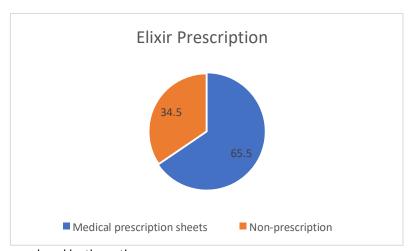


Figure 1. Pau D'Arco Elixir prescription sheets.

Source: produced by the authors.



Table 1. Types of cancer of registered patients.

Items		Absolute	Relative
		f	(%)
Types	of Cancer		
1	Breast	81	36%
2	Prostate	29	13%
3	Pancreas	7	3.1%
4	Large intestine	1	0.4%
5	Thyroid	4	1.7%
6	Stomach	9	3.9%
7	Skin	7	3.1%
8	Throat	4	1.7%
9	Ovary	7	3.1%
10	Uterus	6	2.6%
11	Lung	15	6.6%
12	Ureter	1	0.4%
13	Tongue and lung	1	0.4%
14	Rectum	8	3.5%
15	Spine	1	0.4%
16	Spleen	1	0.4%
17	Myeloma	2	0.8%
18	Salivary glands	1	0.4%
19	Endometrium	1	0.4%
20	Liver	3	1.3%
21	Duodenum	1	0.4%
22	Language	1	0.4%
23	Kidneys	5	2.2%
24	Lower member	1	0.4%
25	Inguinal lymphoma	1	0.4%
26	Gallbladder and liver	1	0.4%



27	Thigh	1	0.4%
28	Cervix	5	2.2%
29	Sarcoma	3	1.3%
30	Intestine	7	3.1%
31	Stomach and Esophagus	2	0.8%
32	Lymphoma	1	0.4%
33	Adenocarcinoma	1	0.4%
34	Leukemia	2	0.8%
35	Gallbladder	2	0.8%
36	Bones	3	1.3%
37	Esophagus	1	0.4%
38	Lung and liver	1	0.4%
39	Common bile duct	1	0.4%
40	Tongue and lymph node	1	0.4%
41	Neck	1	0.4%

f= absolute frequency; % = relative frequency.

Source: produced by the authors.

Regarding the use of Integrative and Complementary Practices (ICPs), the patients mentioned only the use of phytotherapy, highlighting the Elixir of Pau D'Arco, thus indicating the need for greater dissemination of other PICs that can also help in the treatment of patients with neoplasms.

The sociodemographic characteristics of the patients are described in Table 2, including the following variables: gender, age, maintenance of conventional medication and types of cancer.



Table 2. Sociodemographic characteristics of registered patients.

Variables	f	%
Social		
Sex		
Female	131	57.9%
Male	95	42.1%
Age	Average 56 years	-
Continuation of conventional medication		
Yes	225	99%
No	1	1%
Types of cancer		
Breast	81	36%
Prostate	29	13%

f= absolute frequency; % = relative frequency.

Source: produced by the authors.

Of the total records analyzed, most patients were female, consisting of 131 patients (57.9%), of which 81 (36%) had breast cancer, while the male population comprised 95 patients, 42.1% (Figure 2), of which 29 (13%) had prostate cancer.

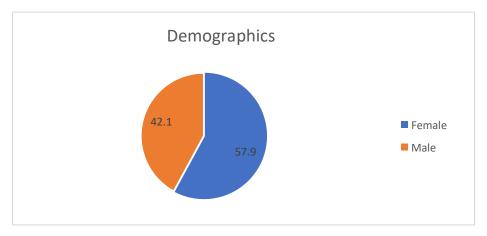
Most patients were merchants, professionals, teachers or civil servants with a mean age of 56 years.

Regarding the therapeutic response to treatment, most patients reported significant improvement with the complementary use of Elixir de Pau D'Arco. Pau D'Arco (Handroanthus avellanedae) is known to be a source of phytochemicals of high curative interest, including lapachol and quinone. The former has been shown to have antitumor properties (stimulating apoptosis of cancer cells and preventing the formation of metastases), anti-inflammatory, immunostimulant, diuretic and antimicrobial properties; the quinone is associated with an action to stimulate the production of blood cells and other blood substances related to coagulation. In addition, the bark of Pau D'Aarco is rich in



flavonoids with known antioxidant, immunomodulatory and anti-inflammatory effects, such as quercetin, and coenzyme Q10, a powerful cell regenerator. The role of lapachol as an antitumor agent has been known for years (FLORIEN, 2021).

Figure 2. Percentage distribution of variables related to the gender of patients with breast (female) and prostate (male) cancer.



Source: produced by the authors.

The antineoplastic drugs mentioned in the patients' records, in addition to the complementary treatment with Elixir de Pau D'Arco, were Tamoxifen and Doxazosin, indicated for breast and prostate cancer, respectively, which coincides with the data on the highest incidence of cancer types in women and men enrolled in the present study. As for other treatments, chemotherapy, radiotherapy, autohemotherapy and surgery were mentioned.

Tamoxifen is widely used in the treatment of breast cancer and is characterized by being a selective estrogen receptor modulator, that is, it blocks estrogen in some tissues of the body but acts like estrogen in others and can be very useful in reducing the risk of breast cancer (Marques; De Gutierrez; De Figueiredo, 2015).

Doxazosin is derived from a quinazoline compound that selectively blocks α -1 adrenergic receptors. This drug is used in the clinic as Doxazosin Mesylate for the treatment of heart and vascular diseases such as hypertension, congestive heart failure, and prostate diseases such as benign prostatic hyperplasia (BPH) (Coelho, 2019).

The use of Levothyroxine Sodium has also been observed, indicated for replacement therapy or hormonal supplementation in patients with hypothyroidism of any etiology. In the case of association with neoplasms, the indications are Suppression of pituitary TSH in the treatment or prevention of various types of euthyroid goiter; thyroid nodules; thyroiditis



subacute or chronic lymphocytic (Hashimoto's thyroiditis); follicular and papillary carcinomas, thyrotropin-dependent thyroid (Ward, 2011).

The use of antidepressants such as duloxetine has been documented. This medication is also indicated for diabetic peripheral neuropathic pain, fibromyalgia, generalized anxiety disorder, chronic low back pain, or osteoarthritis. Use in cancer patients is generally indicated when pregabalin is not tolerated by these patients in the case of neuropathic pain.

The Hypocholesterolemic Rosucor is an aid to diet when there is no adequate response to it and exercise and is associated with high blood cholesterol levels (Karadurmus, 2017).

Some studies show that although the survival rate of cancer patients has recently improved significantly with the emergence of new chemotherapies and advances in radiotherapy, cancer patients are still more susceptible to the cardiotoxic effects developed during treatment, which can significantly increase the morbidity and mortality of this population, especially the symptoms that cardiac problems cause along with the symptoms of oncological treatment (Borges *et al.*, 2018).

In this regard, it can be observed that, in addition to the use of the above-mentioned antineoplastic drugs, other drugs used for heart disease and hypertension were used:

- Ancoron (amiodarone hydrochloride), this substance is intended to regularize cardiac changes related to the heartbeat (arrhythmias), which can occur in some types of diseases (Santana, 2017).
- Nebilet (nebivorol hydrochloride) is indicated for the treatment of high blood pressure and heart failure in the elderly (over 70 years old), with ejection fraction (amount of blood that leaves the heart and travels through the vessels throughout the body when the heart beats) below or equal to 35% (BIOLAB, 2018).
- Eliquis (apixaban) is indicated to prevent blood clots from forming in the blood vessels of the legs (vein thrombosis) and from traveling within the blood vessels and reaching the lungs (pulmonary embolism) or other organs in adult patients who have undergone total hip or total knee replacement surgery (surgery to place a prosthesis) (Santos, 2018).

Another indication for Eliquis is to reduce the risk of stroke, blood clot formation in other blood vessels in the body (systemic embolism), and death in adult patients with atrial fibrillation. It is rapidly absorbed and has an average onset of action between 3 and 4 hours after taking the pill (Santos, 2018).



Thus, the relationship between heart disease and hypertension and the use of anticancer drugs is clearly interrelated, as evidenced by the data from the quantitative research conducted. Most of the drugs mentioned are for use in heart disease and hypertension. For this reason, it is very important that studies are carried out that focus on the cardio-oncology scenario to avoid complications and consequently improve the quality of life of cancer patients who are already so weakened by cancer treatment.

It is important to emphasize that no drug interactions have been recorded with the use of these mentioned medications with the Elixir of Pau D'Arco. Information that a drug interaction is a clinical event that can occur between medication-medication, medication-food or medication-drugs (alcohol, cigarettes and illegal drugs). It is characterized by the interference of one medication, food, or drug with the absorption, action, or excretion of another medication (Oliveira; Filipin; Giardin, 2015).

There have been no reports of adverse reactions to Pau D'Arco Elixir. An Adverse Drug Reaction (ADR) is defined as any harmful or undesirable, unintended response to a drug that occurs at doses normally used in humans for prophylaxis, diagnosis, therapy of disease, or modification of physiological functions (ANVISA, 2011).

A reduction in patient demand for Elixir de Pau D'arco was observed between February and March 2020, which coincided with the onset of the COVID-19 pandemic. Individuals with low immunity, such as those undergoing cancer treatment, are particularly vulnerable to the effects of COVID-19. Therefore, the reduction in demand can be justified as a precautionary measure to avoid exposure.

The final evaluation of the clinical records of patients who used Elixir de Pau D'Arco over a period of four years, from March 2016 to March 2020, revealed the following general results for the 387 patients: 27 were discharged, 226 were still undergoing treatment, 93 gave up treatment, and 41 patients died (Figure 3).

12



Patients who used Elixir

7.00%

58.40%

Cure On treatment Dropout Deaths

Figure 3. Patients who used Pau D'Arco Elixir.

Source: produced by the authors.

No technical and statistical parameters were found in the consulted literature to understand and discuss the results achieved in terms of the number of discharges (cures), continuity and withdrawal of treatment, and mortality. It is well established that, with technological advances in treatments, coupled with a greater understanding of tumor characteristics and complemented by Integrative and Complementary Practices such as Phytotherapy, the perception that cancer invariably leads to death is being dispelled, and patient survival rates continue to increase.

Conclusion

Technological advances, including the development of new drugs, more effective radiotherapy techniques, and less invasive surgical procedures, along with increased public awareness of healthier lifestyles and the incorporation of screening tests into routine care, are essential in preventing cancer or curing it with less complex and less aggressive treatments, as exemplified by this study on phytotherapy. The use of medicinal plants as an alternative treatment for cancer has been gaining traction over time. Some studies have already demonstrated the effectiveness of complementary treatment practices, whether directly to combat cancer or to mitigate its consequences.



Most patients are not aware of Integrative and Complementary Practices, highlighting the importance of increasing adherence to these therapies in oncology. The study observed that all data presented in the records of patients using Elixir de Pau D'Arco were consistent with those in the literature, underscoring the higher incidence of breast and prostate cancer, which also justifies the use of medications such as Tamoxifen and Doxazosin for these types of cancer, respectively.

There was no record of patients using Elixir de Pau D'Arco exclusively as an antineoplastic agent; thus, it did not provide data to analyze the outcomes of this use alone. However, the majority continued using Elixir as a complementary treatment. It is known that Pau D'Arco (Handroanthus avellanedae) is a source of phytochemicals with significant curative potential, including lapachol and quinone.

All the data observed in these records validate the Pau D'Arco elixir as an important complementary therapy in the treatment of cancer, well accepted by patients, with documented improvements. This study is unprecedented and could serve as a model for future research on antineoplastic medicinal plants.

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