PROFILE OF ONCOLOGICAL PATIENTS IN THE ADHERENCE TO THE USE OF ORAL ANTINEOPLASTICS AGENTS

PERFIL DE PACIENTES ONCOLÓGICOS NA ADESÃO AO USO DE ANTINEOPLÁSICOS ORAIS

PERFIL DE PACIENTES ONCOLÓGICOS EN ADHERENCIA AL USO DE ANTINEOPLÁSICOS ORALES

Mário Luan Silva de MEDEIROS[1]
e-mail: mariolsmedeiros@gmail.com

Camilla Ozanan Moreira LOPES[2]
e-mail: cozanan@gmail.com

Victor Almeida SAMPAIO[3]
e-mail: almeidasampaio16@gmail.com

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[1] University Uninassau (UNINASSAU), Mossoró – RN – Brazil. Professor. Doctoral degree in Biochemistry and Molecular Biology (UERN).
[2] University Uninassau (UNINASSAU), Mossoró – RN – Brazil. Bachelor's degree in Pharmacy.
[3] University Uninassau (UNINASSAU), Mossoró – RN – Brazil. Bachelor's degree in Pharmacy.

ABSTRACT: The objective of this study was to analyze and comprehend the profile of oncology patients in their adherence to the use of oral antineoplastic agents in a treatment center. Patient records were utilized to observe patient and treatment characteristics. Additionally, interviews were conducted with healthcare professionals involved in the treatment, and the features of the leading oral antineoplastic agents used by the patients were observed. The average age of the patients was 64 years, predominantly female (61.5%), white (63.3%), married (56.5%), and with incomplete education (35%). The primary types of cancer were breast neoplasms (41.5%), prostatic neoplasms (14.8%), and leukemia (13%). The most frequently used antineoplastic agents were tamoxifen (20%), anastrozole (17.5%), and hydroxyurea (11.8%), with higher adherence to this treatment in 2016 (24.5%) and 2018 (23.8%). Patients undergoing treatment for breast neoplasms, who were clinically stable and had undergone sessions of intravenous chemotherapy, constituted the group that received this therapeutic approach the most.

KEYWORDS: Therapeutic adherence. Antineoplastic agents. Health profile. Drug therapy.

RESUMO: O objetivo deste estudo foi analisar e compreender o perfil dos pacientes oncológicos na adesão ao uso de antineoplásicos orais em um centro de tratamento. Foram utilizados prontuários, observando as características dos pacientes e do tratamento. Além disso, foram realizadas entrevistas com profissionais de saúde relacionados ao tratamento e observadas as características dos principais antineoplásicos orais utilizados pelos pacientes. A média de idade dos pacientes foi de 64 anos, predominantemente do sexo feminino (61,5%), brancos (63,3%), casados (56,5%) e com grau de escolaridade incompleto (35%). Os principais tipos de câncer foram o de mama (41,5%), próstata (14,8%) e leucemia (13%). Os antineoplásicos mais utilizados foram tamoxifeno (20%), anastrozol (17,5%) e hidroxiuréia (11,8%), com maior adesão a este tratamento em 2016 (24,5%) e em 2018 (23,8%). Os pacientes em tratamento para câncer de mama, clinicamente estáveis e que passaram por sessões de quimioterapia endovenosa, constituem o grupo que mais recebe essa abordagem terapêutica.

PALAVRAS-CHAVE: Aderência terapêutica. Agentes antineoplásicos. Perfil de saúde. Terapia medicamentosa.

RESUMEN: El objetivo de este estudio fue analizar y comprender el perfil de pacientes con cáncer en la adherencia al uso de antineoplásicos orales en un centro de tratamiento. Se utilizaron las historias clínicas, observando las características de los pacientes y el tratamiento. Además, se realizaron entrevistas a profesionales de la salud relacionados con el tratamiento. También se observaron las características de los principales antineoplásicos orales utilizados por los pacientes. La edad media de los pacientes fue de 64 años, predominantemente del sexo femenino (61,5%), blancos (63,3%), casados (56,5%) y con escolaridad incompleta (35%). Los principales tipos de cáncer fueron de mama (41,5%), próstata (14,8%) y leucemia (13%). Los antineoplásicos más utilizados fueron tamoxifeno (20%), anastrozol (17,5%) e hidroxiurea (11,8%); con mayor adherencia a este tratamiento en 2016 (24,5%) y 2018 (23,8%). Las pacientes en tratamiento por cáncer de mama, clínicamente bien y que venían de quimioterapia endovenosa, son las que más reciben este abordaje terapéutico.

PALABRAS CLAVE: Adherencia terapéutica. Agentes antineoplásicos. Perfil de salud. Terapia de drogas.

Introduction

According to the International Agency for Research on Cancer, it is estimated that one in every five people globally may develop this ailment over their lifetime. For the year 2025, there is an incidence of over 21 million new cases, with the most prevalent being breast neoplasms (2.5 million) for females, prostatic neoplasms (1.6 million), and trachea, bronchus, and lung cancer (2.5 million). In Brazil, this projection amounts to 687 thousand new cases for the same year (INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, 2023a, 2023b, 2023c, 2023d, 2023e).

The use of oral antineoplastic agents has demonstrated significant progress in various nations, predominantly employed among elderly patients who exhibit mobility limitations and/or in conjunction with other therapeutic modalities (WATSON *et al.,* 2020; PAOLELLA *et al.,* 2018; SCHOTT *et al.,* 2011; WEINGART *et al.,* 2008; LIU; FRANSSEN; WARNER, 1997). This therapeutic approach benefits the patient by utilizing lower single-dose concentrations - resulting in fewer adverse effects, simpler administration - without venous access and reduced economic and social disruption, thus minimizing visits to oncology centers. However, it is essential to emphasize the necessity of multidisciplinary integration, considering the patient's well-being and treatment efficacy (CIRILLO *et al.,* 2019; PAOLELLA *et al.,* 2018; BOONS *et al.,* 2017; SIMONS *et al.,* 2011; WEINGART *et al.,* 2008; GILBAR; CARRINGTON, 2005).

Conversely, non-adherence to oral antineoplastic agents usage mechanisms is linked to federal regulations, medication pricing, formulation methods, hospital screening systems, and patients' medical and social conditions (DEAN *et al.,* 2020). In Brazil, the Ministry of Health, as well as the Brazilian National Health System (SUS) and the Supplementary Health System (SS), are responsible for the distribution of these medications (BRASIL, 2014).

Comprehending adherence to oral antineoplastic agents as a therapeutic approach can strategically enhance the management and planning of these drugs in cancer therapy. This study aimed to describe and analyze the adherence pattern observed in patients diagnosed with cancer, who underwent treatment involving orally administered antineoplastic agents at a specialized institution for oncological diseases.

Method

Data Collection

The present research pertains to a retrospective study of the profile of oncology patients who have been treated or are undergoing treatment through orally administered antineoplastic agents at an oncology treatment center in Rio Grande do Norte, Brazil.

Patient Profile

Understanding the profile of oncology patients treated or undergoing treatment with oral antineoplastic agents was elucidated through electronic medical records, following two structured axes delineated based on the work of Oliveira-Fernandez *et al.* (2014). The first axis, named *patient characteristics*, observed information such as age, gender, cancer type, ethnicity, place of residence, education level, occupation, and marital status. The second axis, named *treatment characteristics*, tracked information like medication, year of adherence, treatment duration, modification of initial treatment, and other therapies. The inclusion criteria for patient screening were: being over 18 years old and having received treatment with oral antineoplastic agents in the last 5 years (between 2016 and 2020). Conversely, exclusion criteria encompassed: children and adolescents or non-consent for participation in the research.

Criteria for Treatment Selection and Distribution

The criteria for selecting and distributing oral antineoplastic agents treatment was evaluated through a structured interview form, targeting professionals responsible for the therapeutic approach to patients (physicians, nurses, nursing technicians, pharmacists, and pharmacy technicians). The interview questionnaire comprised four key questions, with space allocated to include information of interest to the interviewee. Inquiries welcomed, for instance, what is the most common type of cancer in patients receiving this therapy? What is the most utilized oral chemotherapy in these patients' treatment? What is the health profile of patients receiving this therapeutic approach? Why opt for this therapeutic approach?

Inclusion criteria for the interviewees were: holding a position/role linked to the oncology treatment center utilized by the research patients, agreeing to participate in the research, and being involved in some stage of oncology therapy with oral antineoplastic agents. Exclusion criteria encompassed: the inability to respond to at least two questions in the interview questionnaire or refusal to participate in the research.

Pharmacological Characteristics of Antineoplastic Agents

The pharmacological properties of the primary oral antineoplastic agents used by oncology patients at the treatment center were examined. For this purpose, national (Brazilian Health Regulatory Agency – ANVISA *<https://www.gov.br/anvisa/pt-br/assuntos/medicamentos>*) and international databases (such as DrugBank *<https://go.drugbank.com/drugs>* and National Center for Biotechnology Information – *NCBI PubChem <https://pubchem.ncbi.nlm.nih.gov/>*) were employed. Information encompassing the drug's name, indication, and potential adverse effects was delineated.

Data Analysis

The data were tabulated and presented using mean ± standard deviation or percentages about the total variables subjected to analysis. The statistical description of the data was performed using *IBM® SPSS Statistics* (Version 20). Qualitative information derived from the interviews was described and presented in a table.

Ethical Considerations

The study adhered to the Ethical Guidelines of Resolution No. 466/2012. It was submitted to the Research Ethics Committee (via CEP/CONEP) and registered on the *Plataforma Brasil* (No. 4.184.037/CAAE 32520520.0.0000.5294). The exemption from the Informed Consent Form – TCLE – was also submitted and approved by the CEP and authorization for the use of medical records. Regarding interviews with healthcare professionals, a new TCLE was prepared and approved.

Results

Characteristics of Cancer Patients and Their Treatment

A total of 400 medical records of cancer patients were analyzed. The analysis of the records of these patients, who underwent treatment with oral antineoplastic agents between 2016 and 2020, revealed that the mean age was 64 years, with the majority being female (61.5%) and of white (63.3%).

Furthermore, the main types of cancer observed in these patients were breast neoplasms (41.5%), prostatic neoplasms (14.8%), and leukemia (13%), as indicated in Table 1. The municipality of Mossoró (the location of the oncology treatment center), situated in the state of

Rio Grande do Norte, prevailed as the place of residence for the majority of patients (41.5%), most of whom were married (56.6%), engaged in agricultural activities (20.8%), and had incomplete elementary education (35%).

Table 1 – Profile of oncology patients treated or undergoing treatment with oral antineoplastic agents at an oncology treatment center

Variables	
Patient Characteristics	
Age	64,89±17,50
Sex	F (61,5), M (38,5)
Cancer type	Breast Neoplasms (41,5), Prostatic Neoplasms (14,8), Leukemia (13), Myeloma (7,8), Others (22,9)
Ethnicity	White (63,3), Mulatto (27,8), Black (4,3), Undeclared (4,3), Asian (0,5)
Place of residence	Mossoró (41,5), Caraúbas (4,3), Assú (4), Apodi (3,8), Other (46,4)
Education	Incomplete Elementary Education (35), High School (20), Not specified (19,5), Completed Elementary Education (12,3), Completed Higher Education (7,3), Other (6)
Occupation	Agricultural Worker (20,8), Retired (13,3), Homemaker (12,3), Not specified (6,3), Other (47,3)
Marital status	Married (56,5), Single (28), Widowed (13,5), Not specified (1,5), Other (0,5)
Treatment Characteristics	
Medication	Tamoxifen (20), Anastrozole (17,5), Hydroxyurea (11,8), Flutamide (11), Capecitabine (8,3), Others (31,4)
Year of enrollment	2016 (24,5), 2018 (23,8), 2019 (20,8), 2017 (19,3), 2020 (11,8)
Duration	12 months (27), 30 months (14,5), 6 months (13,5), 60 months (12,8), 24 months (10,5), Outros (21,7)
Modification of initial treatment	Yes (72), No (28)
Other treatments (surgery)	Surgery (50,8), No (49,2)

The numerical data represent the percentage of the analyzed variables. Age is presented as the mean ± standard deviation of the examined ages. All data were extracted from medical records of oncology patients treated or undergoing treatment between 2016 and 2020 (n=400) at an oncology treatment center in Rio Grande do Norte, Brazil. Descriptive statistics of the data were performed using the statistical program IBM® SPSS Statistics (Version 20).
Source: Authors' Data

In the evaluation of treatment characteristics, the antineoplastic agents tamoxifen (20%), anastrozole (17.5%), and hydroxyurea (11.8%) were the most frequently observed. The years 2016 (24.5%) and 2018 (23.8%) stood out as having the highest adherence to oral antineoplastic treatment (as shown in Table 1).

Additionally, it was found that 72% of the analyzed patients had modifications in their treatments, including the incorporation of orally administered antineoplastic agents. The implementation of surgical procedures was also identified in 50.8% of patients, and a minimum oral antineoplastic treatment period of up to 12 months was observed in 27% of cases.

Criteria for Treatment Selection and Distribution

According to the data gathered from the interviews with healthcare professionals affiliated with the oncology treatment center, it is evident that patients with breast neoplasms are the ones most frequently subjected to treatment with oral antineoplastic agents, with tamoxifen being the chosen antineoplastic.

Furthermore, the health profile of patients receiving this therapeutic approach is considered through clinical aspects and information derived from intravenous chemotherapy treatment. According to the interviewed professionals, the choice of this therapeutic approach is based on protocols standardized by the Ministry of Health (Table 2).

Table 2 – Analysis of criteria for treatment selection and distribution among oncology patients treated or undergoing treatment with oral antineoplastic agents at an oncology treatment center

Questions	Answers
What is the most common type of cancer in patients receiving this therapy?	Breast Neoplasms
What is the most commonly used oral chemotherapy at the oncology treatment center for treating these patients?	Tamoxifen
What is the health profile of patients receiving this therapeutic approach?	Clinically well patients post-intravenous chemotherapy; Clinically well with favorable test results; Clinically well
Why choose this therapeutic approach?	According to protocols standardized by the Ministry of Health; Hormone therapy is part of the Ministry of Health protocols, usually after intravenous chemotherapy and/or radiation therapy; Hormonal therapy following chemotherapy
Additional Information	No

The data were extracted from structured interview forms, with the interviewees being professionals responsible for the therapeutic approach to oncology patients treated or undergoing treatment at an oncology treatment center in Rio Grande do Norte, Brazil. The interview was conducted with physicians, nurses, nursing technicians, pharmacists, and pharmacy technicians.
Source: Authors' Data

Pharmacological Characteristics of Antineoplastic Agents

The three most commonly used antineoplastic agents among the analyzed oncology patients in the scope of this study were tamoxifen, anastrozole e hydroxyurea. Tamoxifen and anastrozole are indicated for treating breast neoplasms, especially those related to positive estrogen receptors. The third most frequently used oral antineoplastic agent among the evaluated patients was hydroxyurea, meant for treating leukemia and melanoma. All antineoplastic agents have adverse effects, with hydroxyurea having the highest side effects (Table 3).

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Table 3 – Pharmacological characteristics of the leading oral antineoplastic agents used by oncology patients treated or undergoing treatment at an oncology treatment center

	Name of medicine		
	Tamoxifen	**Anastrozole**	**Hydroxyurea**
Recommendation	Treatment of metastatic estrogen receptor-positive breast neoplasms in adults, as well as adjuvant treatment of early-stage estrogen receptor-positive breast neoplasms in adults. Reduce the risk of invasivebreast neoplasms after surgery and radiation in adult women.	Treatment of early breast neoplasms in postmenopausal women. The benefits of anastrozole treatment have been observed in patients with hormone receptor-positive tumors. Reduction in the incidence of contralateral breast neoplasms in patients receiving anastrozole as adjuvant therapy for early breast neoplasms. Treatment of advanced breast neoplasms in postmenopausal women.	Treatment of resistant chronic myelogenous leukemia and melanoma. Hydroxyurea, combined with radiation therapy, is also indicated for treating primary squamous cell carcinoma (excluding lips) of the head and neck and cervical carcinoma.
Adverse effects	Nausea, fluid retention, vaginal bleeding and discharge, skin rash, hot flashes, fatigue.	Hot flashes, asthenia, joint pain and stiffness, headaches, nausea, skin rashes, and depression.	Bone marrow depression (leukopenia, anemia, and thrombocytopenia). Hemolytic anemia. Maculopapular inflammation, facial erythema, peripheral erythema, skin ulceration, cutaneous lupus erythematosus, and skin changes like dermatomyositis. Fever, chills, malaise, asthenia, azoospermia, oligospermia, elevated liver enzymes, cholestasis, hepatitis, and tumor lysis syndrome. Abnormal retention of sulfobromophthalein has been reported. Rare acute lung reactions (diffuse pulmonary infiltrates/fibrosis and dyspnea) have been observed.

The selection of the analyzed oral antineoplastic agents was based on the three most commonly used antineoplastic agents among patients treated or undergoing treatment between 2016 and 2020 at the oncology treatment center in Rio Grande do Norte, Brazil. Data collected between the years 2021 and 2022.
Source: Data collected by the authors[4].

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[4] Data extracted from national databases (Brazilian Health Regulatory Agency – ANVISA (2021a, 2021b, 2021c) and international sources (such as DrugBank (2021) and National Center for Biotechnology Information – NCBI PubChem (2021a, 2021b, 2021c) were utilized.

Discussion

Female breast neoplasms exhibits the highest incidence of new cases and mortality rate, resulting in over 17,000 deaths in Brazil in 2020. Similarly, prostatic neoplasms affects a contingent of more than 70,000 individuals in the country, with over 15,000 deaths registered in the same year (INSTITUTO NACIONAL DE CÂNCER, 2022a; WORLD HEALTH ORGANIZATION, 2020a, 2020b). Breast and prostate cancers emerged as the most prevalent among patients undergoing oral antineoplastic agents treatments, as examined in this study.

Although not among the leading cancer types, leukemia occupied the third position (see Table 1). It's worth noting that for the year 2023, the Northeast region demonstrated the highest rate of new leukemia cases, surpassing 3,000 occurrences, second only to the Southeast region, the most populous, with over 4,000 new cases registered (INSTITUTO NACIONAL DE CÂNCER, 2022b, 2022c). Additionally, advanced age continues to be considered a risk factor for developing various types of cancer (INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, 2021).

In the context of this study, tamoxifen and anastrozole emerged as the most commonly used antineoplastic agents by patients undergoing treatment or already treated for breast neoplasms, followed by hydroxyurea, indicated for leukemia treatment, and flutamide, employed in prostatic neoplasms. The choice of oral chemotherapy to be used by the cancer treatment center is associated with transfers, authorizations, and updates from both the Supplementary Health System (SS) to the Brazilian National Health System (SUS), as well as the guidelines stipulated by the Ministry of Health (MS) and the Brazilian Health Regulatory Agency (ANVISA). Regarding private healthcare, such demand is also subject to the National Regulatory Agency for Private Health Insurance and Plans – ANS (INSTITUTO NACIONAL DE CÂNCER, 2022d; BRASIL, 2013; 2014; 2019a). It's important to highlight that all patients analyzed were treated through the Brazilian National Health System.

There is no observed trend of increasing patient adherence to oral antineoplastic agents treatment during the years analyzed in this study. Adherence to this therapy can be influenced by various social factors such as education level and age, as well as response to previous treatments and the relationship established with healthcare professionals (BARKETT *et al.,* 2022; CIRILLO *et al.,* 2019; PUTS, 2014; SCHOTT *et al.,* 2011).

In addition, oral antineoplastic agents, while highly effective in cancer treatment, can also lead to adverse effects and require rigorous precautions. Thus, the importance of proper management, both by patients and healthcare professionals involved in medicine, is emphasized

(VILLANUEVA-BUENO *et al.,* 2022; MUELLER-SCHOELL *et al.,* 2021; ESCUDERO-VILAPLANA *et al.,* 2019).

As established by Joint Ordinance No. 5 (April 18, 2019) of the Ministry of Health, which approves diagnostic and therapeutic guidelines for breast carcinoma, chemotherapy choice should consider both the clinical characteristics of patients and tumor characteristics. Generally, tamoxifen is recommended for pre and postmenopausal women, and aromatase enzyme inhibitors (such as anastrozole) become treatment options (BRASIL, 2019b). In this study, healthcare professionals involved in oral antineoplastic agents treatment highlighted this standardization set by the Ministry of Health (along with decisions made by the medical team), with tamoxifen being the sole mentioned antineoplastic agent.

Over twelve distinct types of leukemia are identified, with the first four being acute myeloid leukemia, chronic myeloid leukemia, acute lymphoblastic leukemia, and chronic lymphocytic leukemia (INSTITUTO NACIONAL DE CÂNCER, 2022e). For the treatment of chronic myeloid leukemia in adults, agents like hydroxyurea and imatinib mesylate are employed (BRASIL, 2008). Hydroxyurea emerges as the most prevalent oral antineoplastic agents for leukemia treatment in this research.

Patients undergoing treatment or treated for breast cancer (using tamoxifen or anastrozole), older and clinically well, are the ones who most received this therapeutic approach during the analyzed years. Therefore, understanding and mastery of the therapeutic efficacy of orally administered antineoplastics agents and the profile of patients who use them play a pivotal role in optimizing planning and expanding this therapeutic modality at a national level. Furthermore, disseminating this information by the healthcare professional team emerges as an imperative need to increase adherence to this type of treatment.

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