Development and Validation of Educational Material for Guidance on the Use of Ribociclib Succinate in the Treatment of Advanced Breast Cancer

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Desenvolvimento e Validação de Material Educativo para Orientação do Uso do Succinato de Ribociclibe no Tratamento do Câncer de Mama Avançado

Desarrollo y Validación de Material Educativo para la Orientación sobre el Uso de Succinato de Ribociclib en el Tratamiento del Cáncer de Mama Avanzado

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ABSTRACT

Introduction: Cancer is considered a non-communicable chronic disease. Among women, breast cancer is the most common type, generating a significant economic impact on healthcare services. With the increasing incorporation of new technologies, such as cyclin-dependent kinase 4/6 (CDK4/6) inhibitors indicated for the oral treatment of locally advanced breast cancer, the role of the pharmacist has become even more relevant. Low adherence to the proposed therapeutic regimen, mainly due to adverse reactions, can increase the risk of disease progression. Therefore, pharmaceutical care during oncology treatment has become an important strategy to promote safe and effective pharmacotherapy. **Objective:** Develop and validate educational material to guide the use of ribociclib succinate in the treatment of breast cancer. **Method:** Initially, the educational material was developed considering content, language, and visual aspects. It was then evaluated by a panel of expert judges using the Delphi method. To measure the level of agreement, the Content Validity Index (CVI) was calculated using a Likert scale. **Results:** As a result, the booklet was considered validated, with a CVI score of 1. **Conclusion:** It is expected that this educational tool will support the correct and safe use of CDK4/6 inhibitors, promoting knowledge and improving patient adherence to treatment.

Key words: Breast Neoplasms/drug therapy; Enzyme Inhibitors/therapeutic use; Cyclin-Dependent Kinase 4/therapeutic use; Cyclin-Dependent Kinase 6/therapeutic use; Patient Education Handout.

RESUMO

Introdução: O câncer configura-se como uma doença crônica não transmissível. Entre as mulheres, o câncer de mama é o mais incidente, gerando um grande impacto econômico aos serviços de saúde. Com a crescente incorporação de novas tecnologias, como os inibidores de quinases dependentes de ciclinas 4/6 (CDK4/6) indicados como terapia oral do câncer de mama localmente avançado, o trabalho do profissional farmacêutico ganhou ainda mais relevância. A baixa adesão ao esquema terapêutico proposto em razão, principalmente, da ocorrência de reações adversas pode acabar aumentando o risco de progressão da doença. Dessa forma, o cuidado farmacêutico, durante o tratamento oncológico, tornou-se uma importante estratégia para a promoção de uma farmacoterapia segura e efetiva. **Objetivo:** Desenvolver e validar material educativo destinado à orientação do uso do succinato de ribociclibe no tratamento do câncer de mama. **Método:** Inicialmente, o material educativo foi construído considerando aspectos de conteúdo, linguagem e aparência. Em seguida, foi avaliado por um grupo de juízes especialistas no assunto, por meio do método Delphi. Para a mensuração do nível de concordância foi calculado o Índice de Validação do Conteúdo (IVC), por meio do emprego de escala de Likert. **Resultados:** Dessa forma, a cartilha elaborada foi considerada validada, apresentando um valor de IVC igual a 1. **Conclusão:** Espera-se que este instrumento educativo seja uma ferramenta útil para o uso correto e seguro dos inibidores de CDK4/6, atuando na promoção do conhecimento e na adesão das pacientes ao tratamento.

Palavras-chave: Neoplasias da Mama/tratamento farmacológico; Inibidores Enzimáticos/uso terapêutico; Quinase 4 Dependente de Ciclina/uso terapêutico; Quinase 6 Dependente de Ciclina/uso terapêutico; Prospecto para Educação de Pacientes.

RESUMEN

Introducción: El cáncer se considera una enfermedad crónica no transmisible. Entre las mujeres, el cáncer de mama es el tipo más frecuente, lo que genera un gran impacto económico en los servicios de salud. Con la creciente incorporación de nuevas tecnologías, como los inhibidores de las quinasas dependientes de ciclinas 4/6 (CDK4/6), indicados para el tratamiento oral del cáncer de mama localmente avanzado, el rol del farmacéutico ha cobrado aún más relevancia. La baja adherencia al esquema terapéutico propuesto, debido principalmente a la aparición de reacciones adversas, puede aumentar el riesgo de progresión de la enfermedad. De este modo, el cuidado farmacéutico durante el tratamiento oncológico se ha convertido en una estrategia importante para promover una farmacoterapia segura y efectiva. **Objetivo:** Desarrollar y validar material educativo destinado a la orientación sobre el uso del succinato de ribociclib en el tratamiento del cáncer de mama. Método: Inicialmente, el material educativo fue elaborado considerando aspectos de contenido, lenguaje y apariencia. Posteriormente, fue evaluado por un grupo de jueces expertos en el tema, mediante el método Delphi. Para medir el nivel de concordancia, se calculó el Índice de Validez de Contenido (IVC) utilizando una escala de Likert. **Resultados:** Como resultado, el folleto elaborado fue considerado validado, presentando un valor de IVC igual a 1. **Conclusión:** Se espera que esta herramienta educativa sea útil para el uso correcto y seguro de los inhibidores de CDK4/6, promoviendo el conocimiento y la adherencia de las pacientes al tratamiento.

Palabras clave: Neoplasias de la Mama/tratamiento farmacológico; Inhibidores Enzimáticos/uso terapêutico; Quinasa 4 Dependiente de la Ciclina/uso terapêutico; Quinasa 6 Dependiente de la Ciclina/uso terapêutico; Folleto Informativo para Pacientes.

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INTRODUCTION

Breast cancer is caused by the disorganized multiplication of cells that compose the breast tissue[1]. The most commonly reported breast neoplasms are those that attack cells that cover the mammary ducts (*in situ* or invasive ductal carcinoma) or cells within the mammary glands' lobules (*in situ* or invasive lobular carcinoma)[2].

According to the World Health Organization (WHO)[3], breast cancer is the most frequent neoplasm type in women worldwide, being also responsible for the most deaths by cancer in this population. In Brazil, apart from non-melanoma skin cancer, breast cancer is also the most frequent type of neoplasm and the main cause of death by cancer in the female population, with about 73,610 new cases estimated for each year of the 2023-2025 triennium, causing great economic impact to the country's public and private healthcare services, being considered a severe public health issue[4,5].

The choice of therapeutic course of action considers some factors, such as anatomical clinical staging, according to the Classification of Malignant Tumors (TNM)[6], tumoral molecular pattern, through the amount of Human Epidermal Growth Factor Receptor 2 (HER-2) and estrogen and progesterone receptors, and the patient's status. Thus, breast cancer treatment modalities can be divided into local therapies (surgery and radiotherapy) and systemic therapies (chemotherapy, hormone therapy, and targeted therapy)[7].

Over the recent years, with the rise of targeted therapy, a new scenario for breast cancer treatment has been observed, with emphasis on customized therapies that act on the specific molecular characteristics of each tumor. In this scenario, cyclin-dependent kinase 4/6 (CDK4/6) inhibitors, especially ribociclib succinate, make up a new therapeutic alternative for locally advanced or metastatic breast cancer treatment (positive hormone receptor/negative HER-2), in association with an aromatase inhibitor in first line or with fulvestrant in the second line[8,9]. The cyclins control a family of 21 kinases, which play an important role in maintaining the cellular cycle. Ribociclib succinate is a selective inhibitor of cyclin-dependent kinase 4 and 6, which work in the signaling pathways responsible for cellular cycle progression, promoting a reduction in the proliferation of cancer cells[10]. In Brazil, its use has been approved by the National Health Surveillance Agency[11], in addition to being incorporated into the Ordinance N. 73/2021 of the National Committee for Health Technology Incorporation in the National Health System (SUS)[12].

In general, ribociclib succinate is well tolerated, and adverse events are manageable with medication and clinical support, as well as dose adjustment. The daily recommendation is an oral dose of 600 mg, based on a three-week use routine (21 days), followed by a one-week (7 days) pause to allow the patients to recover from any toxicities. Hematological toxicity is the most common event, with neutropenia being the main limiting factor of the dose. Other adverse reactions may also be reported, like cephalalgia, fatigue, cutaneous rash, alopecia, hepatic enzymes alteration, prolongation of the chemotherapy interval, nausea and/or vomiting, constipation and/or diarrhea[13].

The advent of oral antineoplastic therapy allowed for a significant advancement in oncological treatment, bringing more convenience to patients. However, the possibility of non-adherence, or even treatment interruption, is a constant concern among health professionals[14]. Evidence shows that 10% to 50% of patients diagnosed with breast cancer, in use of oral chemotherapy, failed to take their medicine in the correct dosage and through the recommended period[15].

One of the causes that could be related to low adherence or treatment suspension is the presence of adverse effects, which compromise the effectiveness of antineoplastic therapy, increase the risk of disease progression, and health services costs[16]. In this context, the pharmacist becomes an essential instrument for the quality of individualized drug therapy[17].

Through pharmaceutical care, it is possible to guide the appropriate use of prescribed medication, track and manage adverse effects, positively influence therapy adherence, and contribute to self-care and improvement of patients' quality of life[18]. To that end, adopting educational technology is a strategy that can be used[19]. Initiatives gained notoriety in the National Health System over the years. A work developed by Gonçalves et al. resulted in booklets for the treatment of children with acute lymphoblastic leukemia (ALL)[20], in addition to other works that demonstrated their educational role for patients with bone metastases and head and neck cancer[21,22]. However, promoting health education in the scope of oncology requires from patients a set of abilities to interpret and correctly use the information that is made available, called health literacy[23]. Such abilities, in turn, have a significant impact on the understanding of the proposed therapy and its consequent adherence or non-adherence.

Given this context, the development and validation of an educational material targeted at guiding the use of ribociclib succinate for advanced breast cancer treatment is an important strategy to promote education in health, since it aims at improving the quality of the care provided through the use of easy-to-understand information and building a relationship of proximity and trust, thus ensuring a successful therapy.

METHOD

Methodological study conducted from April 2024 to February 2025, in the oncology-reference *Hospital Haroldo Juaçaba*, a private institution that has an agreement with SUS, located in Fortaleza, Ceará, Brazil. The study aimed at developing and validating educational material to guide the use of ribociclib succinate in the treatment of advanced breast cancer.

A booklet was developed containing information targeted at the use of ribociclib succinate and later validated by specialist judges in the field.

The booklet was elaborated considering aspects of content, language, design, and layout. For content definition, the research team consulted databases (PubMed/LILACS/Scopus/SciELO), clinical protocols, therapeutic guidelines from the Brazilian Society of Clinical Oncology (SBOC), and the medication package insert. The language used was adapted for easy understanding, and the booklet was designed in a graphic design platform (Canva), using a layout that enabled the understanding of the available information.

Once developed, the booklet was validated by a judge committee using the Delphi method[24]. This methodology allows for gathering opinions from a group of specialists with the aim of finding a grounded consensus on a certain subject[25].

The judge committee was composed of oncology-specialist pharmacists. Thus, the committee included pharmacists from the oncology reference service who were duly authorized to work in the field, as well as pharmacy students in the first and second year of residency, and excluded external resident pharmacists and pharmacists from other institutions, making a convenience sample of 15 judges.

The judges were contacted through a messaging app (WhatsApp) and invited to participate in the study. Each judge received a copy of the developed booklet (Supplementary Material) and a link for an electronic form hosted in the Google Forms platform, containing the Free and Informed Consent Form (FICF) (Appendix A) and the validation questionnaire (Appendix B) present in the Supplementary Material.

The judges who accepted to participate in the study, after signing the FICF and filling in personal data, evaluated the booklet through the validation questionnaire, composed of 12 questions divided into three groups: objective and relevance, content and language, and appearance.

To measure agreement between judges, the team calculated the Validity Content Index (VCI), a tool that measures the proportion or percentage of judges who agree on certain aspects of the developed booklet[26]. This method employs a Likert-type scale[27], containing a score ranging from 1-4 (1: completely disagree; 2: disagree; 3: agree; 4: completely agree). Thus, the VIC was calculated by the ratio between the number of "3" or "4" responses scored by the judges and the total number of responses. For each group of questions assessed, a VCI value was calculated, and later a general mean was calculated, whose acceptable agreement rate should be equal to or higher than 0.8.

The present study followed the ethical precepts according to Resolution N. 466/2012[28] and N. 510/2016[29] on research with human beings, established by the National Health Council (CNS), submitted to the Research Ethics Committee (CEP) of the *Instituto do Câncer do Ceará* (ICC), approval report number 7.106.994 (CAAE (submission to ethical review): 83285624.0.0000.5528).

RESULTS

The chosen content sought to address the following topics: presentation of the medication and general use guidance, most common adverse effects, most relevant medication interactions, storage recommendations, and main instructions when missing or forgetting to take a dose. Therefore, according to the proposed script, a booklet was built using clear and objective language, in a graphic design platform that allowed the use of an attractive layout to facilitate even more the understanding of displayed information.

As part of the validation process, the developed booklet was submitted to evaluation by a group of specialist judges. This group was composed of 15 pharmacists, of whom ten accepted to participate in the validation process. Of those professionals, six are women and four are men, and the age group ranged from 23-35 years. Moreover, 90% of participants had less than ten years of training. The group was composed of three specialist pharmacists and seven residents, of whom three were in the second year and four in the first year of residency.

After analyzing the developed booklet, the judges responded to 12 questions, which were divided into three sections (objective and relevance – 3 questions; content and language – 4 questions; and appearance – 5 questions), expressing their degree of agreement through a Likert-type scale, composed of a 1-4 scoring (1: completely disagree; 2: disagree; 3: agree; 4: completely agree).

The first section of questions sought to evaluate aspects related to the objective and relevance. Thus, it aimed to verify if the booklet met the goal for which it was created, being relevant to patients using ribociclib succinate.

According to the answers obtained, as shown in Table 1, 90% of the judges attributed a value of 4 (completely agree), while 10% attributed a value of 3 (agree) to the questions that composed the first section, obtaining a VCI value equal to 1.

Table 1. Agreement degree expressed by the group of judges for section 1

Objective and relevance	Completely disagree	Disagree	Agree	Completely agree
Question 1	0	0	1	9
Question 2	0	0	2	8
Question 3	0	0	0	10

The second section of questions sought to evaluate aspects related to the content and language. Thus, it aimed to verify if the information displayed in the developed booklet was in accordance with the scientific literature and capable of helping patients during treatment, encouraging therapy adherence and self-care through clear and objective language.

According to the answers obtained, as shown in Table 2, 87.5% of the judges attributed a value of 4 (completely agree), while 12.5% attributed a value of 3 (agree) to the questions that composed the second section, obtaining a VCI value equal to 1.

Table 2. Agreement degree expressed by the group of judges for section 2

Content and language	Completely disagree	Disagree	Agree	Completely agree
Question 4	0	0	0	10
Question 5	0	0	1	9
Question 6	0	0	1	9
Question 7	0	0	3	7

The third section of questions sought to evaluate aspects related to the appearance of the booklet. Thus, it aimed to verify if the information was displayed in a logical sequence, if the chosen format (booklet) was the most appropriate, if the font type and size, as well as the colors used, were appropriate, and if the chosen illustrations were appropriately related to the text.

According to the answers obtained, as shown in Table 3, 84% of the judges attributed a value of 4 (completely agree), while 16% attributed a value of 3 (agree) to the questions that composed the third section, obtaining a VCI value equal to 1.

Table 3. Agreement degree expressed by the group of judges for section 3

Appearance	Completely disagree	Disagree	Agree	Completely agree
Question 8	0	0	2	8
Question 9	0	0	5	5
Question 10	0	0	0	10
Question 11	0	0	0	10
Question 12	0	0	1	9

Thus, the desired agreement level between the specialist judges was achieved, since the VCI values mean in the three sections was equal to 1. Therefore, the booklet was considered validated for guiding the use of ribociclib succinate in the treatment of advanced breast cancer.

Finally, upon completing the validation questionnaire, the judges were invited to record any compliments, critiques, and suggestions they deemed necessary to improve the developed booklet, as shown in Chart 1.

Figure 1 illustrates the cover of the booklet's final approved version. However, the result of the educational material construction can be viewed in the Supplementary Material.

DISCUSSION

Breast cancer is a chronic non-communicable disease (CNCD), considered a severe public health issue. In Brazil, it is the type of neoplasm that most targets women, causing physical and psychosocial sequelae to those who undergo treatment[30,31].

Over the last decades, there has been an increase in the use of oral antineoplastic drugs for the treatment of breast cancer, bringing more convenience to patients. The iCDK4/6, like ribociclib succinate, belong to a new class of medications that play a significant role in the treatment of advanced breast cancer (positive hormone receptor/ negative HER-2); however, its use requires specific recommendations to establish good clinical outcomes[32].

According to the American Society of Clinical Oncology, the greater the access to oral antineoplastic therapies, the greater the need for strategies to guide the correct and safe use of these medications, since treatment adherence is directly related to the understanding the patient has on their therapeutic regime[33].

Studies show that employing educational tools contribute positively to the teaching-learning process and empowers patients and caregivers, constituting a way of strengthening verbal guidance provided during consultations with health professionals[34-36].

Chart 1. Compliments, critiques, and suggestions proposed by the group of specialist judges

Questions section	Compliments/Critiques/Suggestions
Objective and relevance	"Very relevant material in the guidance of patients" "Excellent material to help patients use ribociclib"
Content and language	"I suggest removing the antibiotics class in the Interactions item. The general public doesn't know what a macrolide or quinolone is, which can cause further doubts. I suggest leaving only the name of antibiotics" "Enriching material with cohesion and clear language"
Appearance	"I suggest standardizing the font and checking the font size for the printed version"

Figure 1. Initial cover of the educational booklet

Therefore, the elaboration of educational materials requires appropriate definition of its creation process[37]. According to Aragão et al.[38], these materials need to be easily managed and understood, be attractive – spark interest and curiosity in the reader –, and be low cost to allow replication.

Sugisaka et al.[39], when elaborating and validating booklets aimed at guidance on the use of oral antineoplastics frequently prescribed for the treatment of breast cancer (anastrozole, tamoxifen, and capecitabine), reinforce the potential of such instruments to promote knowledge, thus contributing to a better understanding of the proposed therapy and the consequent increase in adherence by patients.

An European study on the influence of an information program on treatment adherence, involving women with breast cancer using aromatase inhibitor, showed that patients who received additional information, among them the use of educational leaflets, presented a higher rate of therapy adherence, reinforcing the target audience's understanding of the disease and its treatment[40]. On a national perspective, Gonçalves et al.[21] have already produced an educational material aimed at effective communication to the pediatric population and their families about the proposed treatment. Other works beyond the oncology field also highlight pharmaceutical care boosted by educational booklets[41,42].

Although this booklet has been validated only by pharmacists responsible for dispensing ribociclib succinate, the booklet should also be validated by patients in treatment with CDK4/6 inhibitor, to verify its acceptance, and later, its contribution to these women's adherence to this new class of oral antineoplastic drugs used in the treatment of advanced breast cancer. This limitation shall be rectified in a further study.

Thus, this work, by proposing the development and validation of an educational booklet aimed at guiding the use of ribociclib succinate, innovates by contributing to the dissemination of correct and safe information about new therapies aimed at breast cancer, helping in the understanding of how to use and manage adverse reactions of such medications and promoting increased therapy adherence and the construction of a relationship of trust between pharmacist and patient. These strategies can be widely inserted across health systems.

CONCLUSION

Given the exposed in this work, the outlined objectives were achieved. Thus, a booklet was created to guide the use of ribociclib succinate in the treatment of advanced breast cancer, considering aspects of content, language, and appearance, and was evaluated by a group of expert judges, who presented a level of agreement considered acceptable for validation.

It is therefore expected that this educational tool will support the correct and safe use of CDK4/6 inhibitors, promote knowledge and improve patient adherence to therapy.

CONTRIBUTIONS

All the authors have contributed to the study design, acquisition, analysis and interpretation of the data, wording, and critical review. They approved the final version for publication.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

All the contents associated with the article are included in the manuscript.

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