

Preparation of a Booklet for the Prevention of Pathological Fractures in Patients with Bone Metastases

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Elaboração de uma Cartilha para Prevenção de Fraturas Patológicas em Pacientes com Metástases Ósseas Elaboración de una Cartilla para la Prevención de Fracturas Patológicas en Pacientes con Metástasis Óseas

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ABSTRACT

Introduction: Bone metastases are common in advanced cancer and, when associated with pathological fractures, can impact functionality, quality of life and prognosis. Education practices strengthen health care by incorporating family members and patients into the caring process. Until then, no guidelines for caregivers on care to prevent pathological fractures related to bone metastases were found in the literature. **Objective:** To develop and validate a booklet on care for caregivers of patients with bone metastases to prevent pathological fractures. **Method:** The process of preparing and validating the booklet was carried out in three stages: 1. elaboration of the material based on a literature review; 2. validation of content, appearance and language involving 20 healthcare professionals and ten patient caregivers. The Content Validity Index (CVI) was used to measure the proportion of agreement, with $CVI \geq 0.80$ being considered acceptable; 3. experts panel to evaluate disagreements and suggestions arising from the previous stage. **Results:** An initial version of the booklet was prepared and submitted to content evaluation. All items of the material presented $CVI > 0.90$ in the first round of the evaluation. Additionally, suggestions from participants to improve the booklet through a questionnaire were evaluated, resulting in the acceptance of 65.2% of the suggestions. **Conclusion:** The booklet developed was validated and the suggestions incorporated allowed to reach the most appropriate final model, which will probably help to strengthen guidance to patient caregivers in the process of health care and education.

Key words: Bone Neoplasms; Neoplasm Metastasis; Fractures, Spontaneous/prevention & control; Caregivers; Health Education.

RESUMO

Introdução: Metástases ósseas são frequentes no câncer avançado e, quando associadas a fraturas patológicas, podem impactar na funcionalidade, qualidade de vida e prognóstico. As práticas de educação fortalecem a assistência à saúde ao incorporar familiares e pacientes no processo de cuidado. Até então, não foram encontradas na literatura orientações para os cuidadores sobre os cuidados para a prevenção de fraturas patológicas relacionadas a metástases ósseas. **Objetivo:** Elaborar e validar uma cartilha para cuidadores dos pacientes com metástases ósseas visando à prevenção das fraturas patológicas. **Método:** O processo de elaboração e validação da cartilha foi realizado em três etapas: 1. elaboração do material com base em revisão da literatura; 2. validação de conteúdo, aparência e linguagem envolvendo 20 profissionais de saúde e dez cuidadores de pacientes. Foi utilizado o Índice de Validade de Conteúdo (IVC) para medir a proporção de concordância, sendo considerado aceitável o $IVC \geq 0,80$; 3. painel de especialistas para avaliar discordâncias e sugestões oriundas da etapa anterior. **Resultados:** Uma versão inicial da cartilha foi elaborada e submetida à avaliação de conteúdo. Todos os itens do material apresentaram $IVC > 0,90$ na primeira rodada da avaliação. Adicionalmente, foram avaliadas as sugestões dos participantes no questionário para aprimoramento da cartilha, resultando na aceitação de 65,2% das sugestões. **Conclusão:** A cartilha desenvolvida foi validada e as sugestões incorporadas permitiram chegar ao modelo final mais adequado, o que provavelmente auxiliará no fortalecimento da orientação aos cuidadores de pacientes no processo de cuidado e educação em saúde.

Palavras-chave: Neoplasias Ósseas; Metástase Neoplásica; Fraturas Espontâneas/prevenção & controle; Cuidadores; Educação em Saúde.

RESUMEN

Introducción: Las metástasis óseas son comunes en el cáncer avanzado y, cuando se asocian con fracturas patológicas, pueden afectar la funcionalidad, la calidad de vida y el pronóstico. Las prácticas educativas fortalecen la atención en salud al incorporar a los familiares y pacientes al proceso de atención. Hasta este momento, no se encontraron en la literatura pautas para los cuidadores sobre los cuidados para prevenir fracturas patológicas relacionadas con metástasis óseas. **Objetivo:** Desarrollar y validar una cartilla para cuidadores de los pacientes con metástasis óseas sobre cuidados dirigidos a la prevención de fracturas patológicas. **Método:** El proceso de elaboración y validación de la cartilla se realizó en tres etapas: 1. elaboración del material a partir de una revisión de la literatura; 2. validación del contenido, apariencia y lenguaje en la que participaron 20 profesionales sanitarios y diez cuidadores de pacientes. Para medir la proporción de concordancia se utilizó el Índice de Validez de Contenido (IVC), considerándose aceptable un $IVC \geq 0,80$; 3. panel de expertos para evaluar las disconformidades y sugerencias surgidas de la etapa anterior. **Resultados:** Se elaboró una versión inicial de la cartilla y se sometió a evaluación de contenido. Todos los ítems del material presentaron $IVC > 0,90$ en la primera ronda de evaluación. Además, se evaluaron las sugerencias de los participantes en el cuestionario para mejorar la cartilla, resultando en la aceptación del 65,2% de las sugerencias. **Conclusión:** La cartilla desarrollada fue validada y las sugerencias incorporadas permitieron llegar al modelo final más adecuado, que probablemente ayudará a fortalecer la orientación de los cuidadores de pacientes en el proceso de atención y educación en salud.

Palabras clave: Neoplasias Óseas; Metástasis de la Neoplasia; Fracturas Espontáneas/prevenición & control; Cuidadores; Educación en Salud.

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INTRODUCTION

Cancer is recognized as a world health problem. Overall, the incidence and mortality by disease grow rapidly in the world, reflecting ageing and population growth as well as increased exposure to main risk factors and socioeconomic development of the countries. According to the World Health Organization (WHO), one in each six deaths is disease related and approximately 70% occur in low and middle-income countries. In addition, most of the individuals living in these countries are diagnosed late when the disease is usually at advanced stage. In this context, integrality of care to the patient with cancer makes treatment more effective and less traumatic because the multidisciplinary nature of the approach reduces morbimortality and treatment related complications and when disease evolves, palliative care are essential to promote health related quality of life (HRQoL)^{1,2}.

Bone metastases are common in patients with advanced cancer and account for 90% of malignant bone tumors. They occur in 65% to 80% of the cases of breast and prostate cancer, 40 to 50% of lung malignant neoplasms and less than 10% in malignant gastrointestinal tumors³. When skeletal metastasis occurs, the normal bone remodeling is affected, leading to its destruction and eventually, pathological fractures and other skeletal-related events³⁻⁶.

In clinical practice, the concern with patients with bone metastasis arises from the consequences of these lesions, among which are pain at rest and movement, loss of functionality, global clinical compromise and HRQoL. These conditions are aggravated when they evolve to pathological fractures, causing traumatic impacts, added comorbidities and even lower HRQoL. Rief et al.⁷ reported an incidence of 39% of pathological fractures associated with breast cancer, 22%, with prostate cancer and 22% associated with lung cancer and other solid tumors. The impact of bone metastases and its related events on health system are reflected in increased hospital and family costs and risk of death⁸.

Clinical treatment for patients with bone metastasis encompasses corticotherapy, analgesia, palliative radiotherapy (preventive or occurrence of skeletal related events), bisphosphonates, surgery (in very specific cases) and adaptation to orthoses through physiotherapy. For patients with disseminated bone disease who do not meet surgical criteria, conservative treatment is recommended^{4,9}. In this context, the multidisciplinary team plays a key role in management, referral and biopsychosocial organization of this patient in addition to physiotherapy, indispensable for this group, both for symptoms control and prevention or treatment of pathological fractures¹⁰.

Ideally, these patients should be submitted to early evaluation and follow-up by a physiotherapist in regard to mobilization and postural transfer, risk of falls and fracture, prescription of specific exercises and possible orthoses^{7,11-14}.

Health educational practices are inherent to healthcare, but most of the times are neglected in planning and organization of the services, execution of caring initiatives and management itself⁵. Leaflets, digital media or social media, for instance, are potential resources for patient-centered health education. Education is not limited to dissemination of health related information, but to foster motivation, skills and trust (self-efficacy) required to improve health as well as communication of information about social issues, economic and environmental conditions that affect health and individual risk factors, hazardous behavior and use of the health system. According to Echer¹⁶, manuals are prepared to strengthen the guidance to families and patients in the caring process and health education. So far, practical care guidance for caretakers of patients with bone metastasis to prevent pathological fractures have not been found in the literature.

In addition to specific clinical approaches, health education initiatives are required to improve the autonomy of patients to care for themselves and provide more information about prevention and treatment of specific conditions¹⁵. The objective of this article is to elaborate and validate an educational material on management and care addressed to caretakers of patients with bone metastases to prevent pathological fractures.

METHOD

Qualitative and quantitative methodological research developed from June to November 2022.

The process of elaboration and validation of a booklet for caretakers of patients with bone metastases followed the three phases according to Giordani (Figure 1)¹⁷. All the participants signed the informed consent form (ICF).

The Ethics Committee of the National Cancer Institute (INCA) approved the study, report number 4,750,882 (CAAE (submission for ethical review) 46785521.0.0000.5274) in compliance with Directive 466/12¹⁸ of the National Health Council (CNS) for studies with human beings. The software Statistical Package for Social Science for Windows (SPSS, São Paulo, Brazil)¹⁹ version 21.0 was utilized to analyze the quantitative data.

FIRST STAGE: ELABORATION OF THE BOOKLET

Elaboration of the theoretical content and production of the graphic design of the booklet^{17,20} based on the

current scientific literature, clinical experience of the professionals in charge of the elaboration and clinical and demographical profile of patients with advanced cancer and bone metastases assisted at INCA's "*Hospital de Câncer IV (HCIV)*" and enrolled in the retrospective cohort observational study earlier developed¹³.

The first version of the booklet attempted to guide caretakers on the management of patients with bone metastases to prevent pathological fractures.

SECOND STAGE: VALIDATION OF THE CONTENT, APPEARANCE AND LANGUAGE

The first version of the booklet was presented to the caretakers of patients with bone metastases, to nurses and physiotherapists with at least ten years of experience in palliative care and oncology; after reviewing the content, the appearance and language they responded to a Likert-scale structured data collection questionnaire explained ahead.

Ten caretakers of patients with bone metastases admitted to the wards and outpatient unit of HCIV/INCA have been invited. The first version of the booklet and the printed data collection questionnaire were utilized, literacy was a condition to respond to the questionnaire. The investigator was available to respond to any question or doubts about the booklet and questionnaire.

In addition, ten nurses and ten physiotherapists were invited and responded to an online evaluation questionnaire through Google Forms. The professionals were selected based on the years of experience at INCA, clinical experience and availability to join the study.

The questionnaire consisted of closed and open fields to accept suggestions from the interviewees, report difficulties and disagreements with the content, visual presentation and language utilized in the booklet because, ultimately, the material should be easy-to-understand, objective and attractive.

The Likert scale created by Rensis Likert in 1932 was utilized, the interviewees responded to the affirmations proposed by the investigator, stating their score of agreement that best reflected their opinions. The range of the scale is wide and the middle position reflects an average value of the attribute to avoid any double interpretation²⁰.

The Content Validity Index (CVI) that measures the proportion of agreement with the questionnaire was utilized. For the Likert scale, the calculation is made utilizing the number of equivalent responses and absolutely equivalent divided by the total number of responses. The acceptable agreement grade should be at least 0.80 (preferably higher than 0.90)²¹.

THIRD STAGE: EXPERTS PANEL

After the results of the questionnaire were compiled, a group of three oncologic palliative care experts with more than ten years of experience analyzed critically the disagreements and suggestions and adjusted the material to meet the objectives proposed: to address the demands of caretakers of patients with bone metastases related to the correct mobilization of the patient and a tool that facilitates the assistance.

The booklet was presented to the group as well as the results of the questionnaire applied in the second stage. Next, a structured script to discuss the items and mainly the disagreements detected in the second stage was followed. The experts panel modified the items and developed new ones, when necessary.

The experts met in November 2022 with a moderator who recorded all the decisions and the final version of the booklet was created.

RESULTS

FIRST STAGE

The first version was titled: "How to provide care to a patient with bone metastasis: booklet with guidelines to prevent fractures", elaborated with simple language, demystifying specific aspects of cancer evolution, bone metastasis and pathologic fracture for better understanding by the target public. Practical guidelines on how to mobilize the patient at bed, postural transfer, indication and use of orthoses and exercises were prepared as well. In addition, explanatory figures of each item presented were utilized.

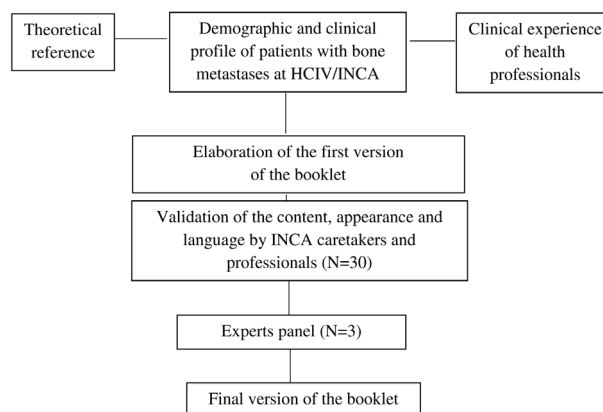


Figure 1. Flowchart of the elaboration process and validation of the booklet

Source: The authors based on Giordani¹⁷.

Captions: HCIV = *Hospital do Câncer IV*; INCA = National Cancer Institute.



SECOND STAGE

Responses of 30 participants have been collected, being: ten caretakers of patients with bone metastases at HCIV/INCA, ten nurses of HCIV/INCA and ten physiotherapists of several units of INCA.

The CVI presented satisfactory results with scores above 0.90 (Table 1).

THIRD STAGE

Even with the high agreement level according to the CVI, the participants suggestions were evaluated to improve the content, 65.2% of the suggestions have been accepted. Table 2 portrays the result of the decisions made during the meeting with the experts panel. The material has 16 pages and was delivered to the governance of the institution for printing as a booklet and electronic distribution, figure 2 presents a copy of the cover of the final booklet.

The final booklet is available at the repository *Ninho*²².

DISCUSSION

Health education practices are inherent to work in health¹⁵, they are important tools to promote health because in addition to ensuring essential rights, they stimulate patient-centered interventions, focusing on the population needs and allowing them to manage their basic demands and become less dependent from health professionals as long as they are in possession of relevant information²³. The experience of the professionals involved, theoretical knowledge and study of cohort prior to the booklet¹³ allowed the elaboration of this material to prevent pathological fracture of patients with bone metastases.

The main motivation behind the elaboration of the booklet was the high prevalence of patients with bone metastases referred annually to HCIV/INCA¹³, the necessity of a facilitating tool to provide care to these patients at home, in addition to reinforcing, keep and standardize the guidance obtained from clinical practice at hospitals, home or outpatient unit, improving the communication with the target public, avoiding loss of information (then communicated verbally only) and serving as source of reference in view of future necessities²³.

According to Pereira et al.²⁴, the perception caretakers have of patients with advanced cancer can be affected along the sickening process because they are part of several aspects of the patient life and face daily challenges and difficulties to understand the decisions of the health team.

Table 1. Content Validity Index of the booklet (N=30)

Variables	CVI
Booklet cover	
Language	0.96
Graphical presentation	1
Presentation of the booklet	
Language	1
Explanatory figures	1
Content	1
Definition of bone metastases	
Language	0.96
Explanatory figures	0.96
Content	1
Definition of pathological fractures	
Language	1
Explanatory figures	1
Content	1
What needs to be done to minimize the likelihood of sustaining a fracture?	
Language	0.96
Explanatory figures	0.96
Content	1
How to detect a fracture?	
Language	1
Explanatory figures	1
Content	1
What type of care can be provided to the patient with bone metastases?	
Language	1
Explanatory figures	1
Content	1
Continuation of the care provided to the patient with bone metastases	
Language	1
Explanatory figures	1
Content	1
2 - Continuation of the care provided to the patient with bone metastases	
Language	1
Explanatory figures	0.96
Content	1

To be continued



Table 1. Continuation

Variables	CVI
3 - Continuation of the care provided to the patient with bone metastases	
Language	1
Explanatory figures	1
Content	1
How to manipulate the patient at bed?	
Language	1
Explanatory figures	1
Content	1
2 - How to manipulate the patient at bed?	
Language	1
Explanatory figures	1
Content	1
How to seat the patient with the legs out of the bed?	
Language	1
Explanatory figures	1
Content	1
How to transfer the patient to the wheel chair?	
Language	1
Explanatory figures	1
Content	1
How to transfer the patient from the wheel chair back to the bed?	
Language	1
Explanatory figures	1
Content	1
What should be avoided for patients with bone metastases?	
Language	1
Explanatory figures	1
Content	1
Does my patient need vest, cervical collar or other devices?	
Language	0.96
Explanatory figures	1
Content	1
Doubts and comments	
Language	1
End of the questionnaire	
Overall theme addressed in the booklet	1

Captions: CVI = Content Validity Index.



Figure 2. Booklet's cover

Source: INCA²².

The participation of physiotherapists and nurses in this process favored a constructive critique to refine the guidelines under a different perspective according to the expectations of each category because they can have different interests and perspectives of those who created the material²⁵.

During the approach, the professionals attempt to encourage the patients providing specific information and instructions and bringing them into the treatment program to motivate them to “control” the disease²⁶.

The caretakers' evaluation of the patients allowed to understand the needs of who needs guidance related to direct care to the patient, in order to meet the expectations utilizing an accessible tool to support the care to be provided. It was important to value their opinion and perception and grant them the opportunity to express themselves and present suggestions on the content, language, layout; this step was critical to empower them with clear and understandable information about the health condition, collect the suggestions and be aware of the difficulties of practical approach of the patient to improve the adhesion to the care proposed²⁷.

The participation of the caretakers in this process is in accordance with the concept of patient-centered care, one of the basic principles of an effective care²⁶.



Table 2. Suggestions to change the booklet and decisions taken (N=30)

Suggestions	Decision	Suggestions	Decision
Cover		Continuation of the care provided to the patient with bone metastases? page 10	
Remove the pronoun 'mine' of the title	Accepted	Human figures should be the same in the entire booklet	Rejected
Replace 'patient' for 'individuals'	Rejected	Continuation of the care provided to the patient with bone metastases? page 11	
Remove the word 'pathologic' from 'pathological fracture'	Accepted	The couch in the last figure was not shown	Accepted
Put White and Black individuals instead of two White individuals – inclusion	Accepted	Continuation of the care provided to the patient with bone metastases? page 12	
Present a patient without crutches	Rejected	Grammar suggestions	Accepted
Keep only the title and incorporate the subtitle	Accepted	Add that the headboard should be at 45 degrees to facilitate feeding the patient	Accepted
Presentation of the booklet		Place birdseed pillow under bone prominences	Rejected
Choose another patient, the patient portrayed is a young female	Rejected	Include change of supine position every two hours or according to the patient's tolerance	Accepted
Grammar suggestions	Accepted	How to manipulate the patient at bed? page 13	
Definition of bone metastases, page 5		Insert images at each stage	Rejected
Grammar suggestions	Accepted	Grammar suggestions	Accepted
Generalize primary tumor, the example utilized was breast cancer	Rejected	How to seat the patients with the legs out of the bed? page 15	
Change a photo of the knee for a photo of the spine to exemplify BM	Accepted	Include 'stay seated for a few minutes before moving to the chair'	Accepted
Utilize the word 'neoplasia' instead of 'tumor'	Rejected	How to transfer the patient to the wheel chair? page 16	
Grammar suggestions	Accepted	Utilize belt for transferences	Rejected
Definition of pathological fractures, page 6		Check whether the chair is locked	Accepted
Keep only the figure of total fracture	Rejected	Include the physiotherapist or professional taking care of the patient	Accepted
Include pressure lesion and DVT as complications	Accepted	How to move the patient from the wheel chair back to the bed? page 17	
Replace 'rupture' for 'fracture'	Accepted	Avoid putting weight on the limb due to risk of fracture	Accepted
Grammar suggestions	Accepted	Add a figure at the end of the page	Accepted
What needs to be done to reduce the likelihood of the patient sustaining a fracture? page 7		Include the utilization of plank for transference	Rejected
Physiotherapist evaluation should come first	Accepted	Grammar suggestions	Accepted
Guide the patient to take medication only if prescribed by the doctor	Accepted	What to avoid in patients with bone metastases? page 18	
Change the image that appears to be of a child	Accepted	Standardize the drawings of that page	Accepted
Grammar suggestions	Accepted	Does my patient need vest, cervical collar or other devices? page 19	
How to discover whether the patient sustained a fracture? page 8		Change the word 'orthoses' for 'adapter'	Rejected
Include bruises as sign of fracture	Rejected		
Grammar suggestions	Accepted		
Include seeking for emergency assistance when signs and symptoms are observed	Accepted		
Change the word 'intense' for 'very strong' pain	Accepted		
Definition of the care provided to the patient with bone metastases, page 9			
Standardize the figure	Accepted		

Captions: BM = Bone Metastasis; DVT = Deep Vein Thrombosis.

It was important to adjust the material to the sociodemographic profile of patients assisted by HCIV/INCA to create the booklet, as the institution assists individuals with low level of education at the most¹³. The construction of a clear, short, easy-to-read material with illustrations had the objective of making the understanding and communication effective, expanding the knowledge and promoting a dialogue among health professionals and patients to support the motivation to continue reading the booklet²⁴.

A potential limitation was the construction of a booklet based partially on the experience of professionals, which could lead to professional bias. However, this fact was minimized with the subsequent stages and the selection of experienced professionals in cancer management, mostly in relation to physiotherapy provided in different INCA facilities.

So far, this booklet is unprecedented in Brazil and an important tool to manage and care to patients with bone metastasis, since pathological fracture imposes considerable morbidities to the patient and although in this study it did not influence global survival, it is a negative condition affecting HRQoL²⁸.

The booklet was elaborated in a specialized and reference institution in caring for patients with cancer, which is one the strengths of the study, further to the evaluation of the patients by the caretakers. Furthermore, the material can be used in other public and private institutions.

The construction of the booklet was proven to be feasible, combining the theoretical content, the results of the base study about the clinical and sociodemographic profile of the patients with bone metastasis assisted at HCIV/INCA with the necessities revealed in clinical practice, which can be applied in the elaboration of materials for health education and updating, ensuring the adequacy of the content based on the participants suggestions^{25,28}.

CONCLUSION

Patients with bone metastases are more susceptible to pathological fractures with direct impact on prognosis and quality of life. The creation of a booklet with guidelines to prevent these fractures will allow better management of care and help the caretaker to perform their tasks safely.

The booklet “How to provide care to a patient with bone metastasis: booklet with guidelines to prevent fractures” presented high CVI and, consequently, is valid to be utilized by caretakers of patients with bone metastases.

CONTRIBUTIONS

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

DECLARATION OF CONFLICT OF INTERESTS

The author Anke Bergmann, the scientific-editor of INCA's *Revista Brasileira de Cancerologia*, has potential conflict of interests. The other authors have no conflict of interests to declare.

DATA AVAILABILITY STATEMENT

All content underlying the text is contained in the manuscript.

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