Construction and Validation of a Care Protocol for Critical Patients with Cancer in Delirium

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Construção e Validação de um Protocolo de Cuidados para Pacientes Críticos com Câncer em Delirium

Construcción y Validación de un Protocolo de Atención al Paciente Crítico con Cáncer en *Delirium*

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ABSTRACT

Introduction: The frequency of *delirium* in oncology intensive care units is high. **Objective:** To build a care protocol for cancer patients with *delirium* admitted to an intensive care unit and investigate its face and content validity. **Method:** Descriptive study conducted in 2016 in a high complexity care center in oncology located in the city of Rio de Janeiro, Brazil. A committee formed by 43 judges assessed the face and content validity of the protocol that was built from the recommendations contained in the Clinical Practice Guidelines for the Management of Pain, Agitation, and *Delirium*. The content validity index and the proportions of pertinence and compliance of each item of the protocol were calculated. **Results:** All 19 items had a content validity index >0.80 and proportions of compliance greater than 95%. The relevance ratio of each item ranged from 86% to 100%. **Conclusion:** The protocol presented adequate face and content validity, being promising for the management of *delirium* in cancer patients admitted to an intensive care unit.

Key words: Delirium; Intensive Care Units; Cancer Care Facilities; Validation Study.

RESUMO

Introdução: A frequência de *delirium* em unidades de terapia intensiva oncológica é elevada. **Objetivo:** Construir um protocolo de cuidados para pacientes com câncer em *delirium*, internados em uma unidade de terapia intensiva e investigar sua validade de face e de conteúdo. **Método:** Estudo descritivo realizado em 2016 em um centro de assistência de alta complexidade em oncologia localizado na cidade do Rio de Janeiro, Brasil. Um comitê formado por 43 juízes apreciou as validades de face e de conteúdo do protocolo que foi construído a partir das recomendações constantes no *Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium*. Calcularam-se o índice de validade de conteúdo e as proporções de pertinência e de conformidade de cada item desse protocolo. **Resultados:** Todos os 19 itens obtiveram índice de validade de conteúdo >0,80 e proporções de conformidade superiores a 95%. A proporção de pertinência de cada item variou de 86% a 100%. **Conclusão:** O protocolo apresentou adequadas validades de face e de conteúdo, mostrando-se promissor no manejo do *delirium* em pacientes com câncer internados em unidade de terapia intensiva.

Palavras-chave: Delírio; Unidades de Terapia Intensiva; Institutos de Câncer; Estudos de Validação.

RESUMEN

Introducción: La frecuencia del *delirium* en las unidades de cuidados intensivos oncológicos es alta. **Objetivo:** Elaborar un protocolo de atención para pacientes oncológicos con *delirium* ingresados en unidad de cuidados intensivos e investigar su validez aparente y de contenido. **Método:** Estudio descriptivo realizado en 2016 en un centro de atención de alta complejidad en oncología ubicado en la ciudad de Río de Janeiro, Brasil. Un comité formado por 43 jueces evaluó la validez aparente y de contenido del protocolo que se construyó a partir de las recomendaciones contenidas en el *Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium*. Se calculó el índice de validez de contenido y las proporciones de pertinencia y cumplimiento de cada ítem del protocolo. **Resultados:** Los 19 ítems tenían un índice de validez de contenido >0,80 y proporciones de cumplimiento superiores al 95%. El índice de relevancia de cada ítem osciló entre el 86% y el 100%. **Conclusión:** El protocolo presentó una adecuada validez aparente y de contenido, y se mostró prometedor en el manejo del *delirium* en pacientes con cáncer ingresados en una unidad de cuidados intensivos.

Palabras clave: Delirio; Unidades de Cuidados Intensivos; Instituciones Oncológicas; Estudio de Validación.

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INTRODUCTION

Delirium corresponds to an acute neurologic disorder characterized by transitory alterations of the conscience and of cognition observed frequently in patients admitted in Intensive Care Units (ICU). The prevalence of this phenomenon is nearly 70% and the incidence can reach until 89% in non-specialized ICU's[1-3]. In oncologic ICU's the prevalence and incidence of *delirium* are also high, specially in patients in mechanic ventilation, respectively, 95%[4] and 64.6%[5].

In addition, patients developing *delirium* use to present worse results in the evolution, which contributes for the increase of the hospitalization length, higher risk of occurrence of adverse events as respiratory and neurologic complications in addition to more mortality[1-3].

In order to contribute for the implementation of strategies of evaluation, prevention, and treatment of the *delirium* in critical environments, the goal of this study was to build a management protocol for patients with cancer in *delirium* admitted at the ICU and investigate the face and content validity.

METHOD

Methodological, descriptive study conducted between October and December 2016 at the ICU of a high complexity oncologic unit in the city of Rio de Janeiro, Brazil.

For the elaboration of the management protocol, the recommendations of the Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium[6] were utilized from which relevant items were selected, being the relevance confirmed by extensive literature review that the authors performed. The 19 items selected were distributed in the dimensions titled "Pain and Analgesia", "Agitation and Sedation" and "Management Strategies".

A committee of judges formed by nurses, physicians, and physiotherapists applied the Delphi[7] technique for face and content validation of the protocol. The criteria to select the judges were time of practical experience in intensive therapy greater or equal to five years and time of work in the scenario of the study greater or equal to one year.

Therefore, 47 judges received a letter-invitation, Informed Consent Form (ICF) and link to access the first version of the protocol by e-mail, messages app or from the main author of the study. In this stage, the judges were instructed to evaluate the format and content of the protocol through the analysis of the items selected for its construction by a questionnaire where comments and suggestions should be presented. Regarding the appropriateness of each item in the protocol, the judges should mark one of the following options of the questionnaire: "agree" or "disagree". In relation to the level of importance of each item, the judges should mark one of the following options of the questionnaire: "not important", "important" or "very important".

43 judges returned the ICF signed, and the questionnaire completed within the determined time (until 20 days). Next, the content validity index (CVI) was calculated to measure the proportion of judges who concurred with the level of importance of each item classified as "important" or "very important", being considered valid those obtaining the minimum value of 0.80 of concurrence among the judges[8].

Comments and suggestions of the judges presented in the previous stage were considered in the next, when some items were redrafted, and a new item was included in the protocol. Next, the revised version of the protocol was submitted to the 43 judges for a new review who returned the questionnaire in until ten days after receiving by e-mail, messages app or from the main author of the study. In the questionnaire, the judges responded "yes" or "no" about the conformity of the protocol items for clarity and how the items were grouped, the cohesiveness of the items presented and respective responses, their objectivity and easiness of reading and understanding according to the proposal of evaluation of conformity suggested by Pasquali[9].

The Institutional Review Board of the Federal University of the State of Rio de Janeiro (Report 1.769.591) and of the National Cancer Institute José Alencar Gomes da Silva (Report 1.776.393) approved the study in 2016.

RESULTS

The Committee consisted of 22 nurses, 16 physicians and five physiotherapists, mostly females (67.4%). The mean age of the judges was 40.7 years (standard-deviation: 7.0) and mean time of practical experience in intensive therapy of 14.4 years (standard-deviation: 2.0). All of them were graduated in intensive therapy, 27.9% completed the MSc degree and 7.0%, PhD.

The first version of the protocols evaluated by the Committee is presented in Chart 1.

About the appropriateness of each item in the protocol, the proportion of the judges concurrence ranged from 86% to 100%, and for 14 of the 19 items, the proportion was ≥ 95%. According to Table 1, all the items of the first version of the protocol reached CVI >0.80.

Judges' comments and suggestions about the format and content of the protocol determined the redrafting of

Chart 1. First version of the protocol

Pain and Analgesia	1. Incidence of pain (consider oncologic pain)
	2. Evaluation of the pain (preferentially, utilize the Behavioral Pain Scale[10] for patients sedated or the analog visual scale for non-sedated)
	3. Treatment/Control of the pain
Agitation and Sedation	4. Programmed and observed daily awakening
	5. Avoid abusive use of sedative medication in bolus
	6. Monitoring of the depth of the sedation (utilize the Richmond Agitation-Sedation Scale[11])
	7. Choice of the sedative
Management strategies	8. Detection and monitoring of the *delirium* (utilize the Confusion Assessment Method for Intensive Care Unit[12])
	9. Whenever possible, perform early mobility efforts
	10. Keep temperature consistent with the person's condition
	11. Avoid restrictive bandages; if necessary, prefer boxing gloves
	12. Allow a companion whenever possible
	13. Favor postoperative visit for eligible surgery
	14. Wear hearing protection after assessment of the personal condition
	15. Keep indirect light and install luminosity control devices
	16. Keep hearing prosthetics and allow glasses and other personal objects whenever possible
	17. Avoid tv and radio after midnight (when approved, use earphone)
	18. Keep curtains open during daytime whenever possible for the patient to know day from night
	19. Utilize digital wall clocks for the patient to know day and night hours

some items as the 14 and 17 and even their combination, as the case of item 18 which, although having reached CVI of 1.00, it was combined with item 15, whose CVI was 0.95 (Table 1). In addition, a new item was added about comfort (item 19) since 11.6% of the judges recommended its inclusion in the final version of the protocol presented in Chart 2.

Table 1. Content validity index of the first version of the protocol

Item	CVI
1. Incidence of pain (consider oncologic pain)	1.00
2. Assessment of pain (preferably, use the Behavioral Pain Scale[10] for sedated patients or the visual analog scale for non-sedated)	0.97
3. Treatment/control of pain	1.00
4. Daily awakening programmed and observed	1.00
5. Avoid abusive use of sedative medications in bolus	0.97
6. Monitor the depth of the sedation (utilize the Richmond Agitation-Sedation Scale[11])	1.00
7. Choice of the sedative	1.00
8. Detection and monitoring of the *delirium* (utilize the Confusion Assessment Method for the Intensive Care Unit[12])	1.00
9. Whenever possible, perform early mobility efforts	1.00
10. Keep adequate temperature according to the individual's condition	1.00
11. Avoid the use of bandages for restriction: if necessary, prefer boxing gloves	1.00
12. Allow the presence of a companion whenever possible	0.97
13. Favor visit to postoperative unit in cases of eligible surgery	0.97
14. Wear hearing protection after evaluation of the personal condition	0.81
15. Keep indirect light and install luminosity control device	0.95
16. Keep hearing prosthetics and allow glasses and other personal objects whenever possible	1.00
17. Avoid tv and radio after midnight (when indicated, use earphone)	0.95
18. Keep curtains open during daytime for the patient to know day from night	1.00
19. Utilize digital wall clocks for the patient to know day and night hours	1.00

According to the proposal of conformity assessment suggested by Pasquali[9], all the items of the final version of the protocol presented proportions of conformity higher than 95% (Table 2).

Chart 2. Final version of the protocol

Pain and Analgesia	1. Evaluate the incidence of pain (consider oncologic pain)
	2. Evaluate the pain (preferably, utilize the Behavioral Pain Scale[10] for patients sedated or analog visual scale for non-sedated)
	3. Treat the pain
Agitation and Sedation	4. Schedule the daily awakening programmed and observed aiming goal-driven sedation
	5. Avoid abusive use of sedative drugs in bolus
	6. Monitor the depth of the sedation (utilize the Richmond Agitation-Sedation Scale[11])
	7. Select correct sedative
Strategy of Management	8. Detect and monitor *delirium* (utilize the Confusion Assessment Method for the Intensive Care Unit[12])
	9. Perform early mobility efforts as soon as possible
	10. Keep body temperature matched to the patient's status
	11. Avoid bandages for mechanic contention; if necessary, prefer boxing gloves type
	12. Allow the presence of companion whenever possible
	13. Allow prior visit to the postoperative unit in case of eligible surgery
	14. Minimize and manage ambient sounds
	15. Allow natural light for the patient to know day from night, and at evening, reduce luminosity whenever possible
	16. Keep hearing prosthetics and allow glasses and other personal objects whenever possible
	17. Avoid the use of tv and radio after 10 P.M. (when applicable, wear earphones)
	18. Utilize digital wall clock for the patient to tell day from night
	19. Provide comfort

Table 2. Conformity of the items of the final version of the protocol

Conformity	Yes (%)
Are the items presented in conformity with the criteria of objectivity? – wrong or right response	100
Are the items presented in conformity with the criteria of simplicity? – only one idea must be expressed	98
Are the items presented in conformity with the criteria of clarity? – must be understandable	98
Are the items presented in conformity with the criteria of variety? – standardization of terms makes reading confused, tiresome, and monotonous	98
Are the items presented in conformity with the criteria of typicality? – phrases with expressions matched to the theme	100
Are the items presented in conformity with the criteria of comprehensiveness? the set of items should cover the entire magnitude of the theme	96

DISCUSSION

The results of the study show that the final version of the protocol for patients with cancer in *delirium* admitted at the ICU consists of applicable and important items grouped clearly and cohesively regarding objectivity and easiness of reading and understanding. Based in these results, it is believed that the protocol has the potential to collaborate for the management of *delirium* for critical patients with cancer.

A systematic review[13] concluded that programs of implementation of strategies for the evaluation, prevention, and treatment of *delirium* in ICU integrated to actions of management of pain and agitation[6], as the protocol investigated in this article have the potential to improve the clinical results of the patients.

The first item of the protocol addressed the evaluation of the pain, including the oncologic pain. This emphasis was given because oncologic pain is characterized by simultaneous feelings of acute and chronic pain associated with the dissemination of tumor cells in the body or for being the consequence of a modality of cancer treatment or having been provoked by other disease related conditions as tumor wound, for example[14]. Therefore, it is paramount that professionals working in oncologic ICU consider the evaluation of the pain because, in addition to being a triggering factor of *delirium* when neglected[15], is described as an intense and unbearable feeling accompanied by sleeping difficulty and irritability[14].

In addition to the protocol having considered the evaluation of the oncologic pain, the judges suggested the inclusion of another item which addressed the comfort of the patient. The comfort has already been pointed out in a previous study as an important topic to be monitored while managing *delirium* in ICU. It is known that comfort is influenced by the physical, psychospiritual, social and environmental contexts which, remarkably is influenced by luminosity, sound, and temperature conditions[16], that have specific characteristics in the ICU: constant noises (from heart monitors, mechanic ventilators and drugs infusing pumps), unpleasant odors, intense artificial illumination and cold temperature[17]. Although items 14 and 15 address the control of sounds and luminosity, the

importance of comfort in the protocol is justified since the diagnosis of cancer brings the conscience of risk of death that can be followed by anguish and fear, impacting the patient's comfort[18].

Excepting the items about oncologic pain and comfort, the other were constructed from the recommendations of the Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium[6], which advises the best practices for pain, agitation, and *delirium* management in order to improve the clinical results of patients admitted in ICU. Therefore, the management protocol was developed with the purpose of contributing for the standardization of conducts of care for critical oncological patients, so the intensivists are able to follow it. The reason is that while managing and controlling other frequent phenomena in ICU, prevention programs with grouped recommendations or combination of good practices have already presented more positive results than isolated actions or recommendations[19].

CONCLUSION

Although future investigations are necessary to evaluate the practical application and feasibility of the management protocol, it presented correct face and content validities showing to be a promising tool for management of *delirium* in patients with cancer admitted in ICU.

CONTRIBUTIONS

Bárbara Rocha Gouveia contributed for the study conception and design, data analysis, interpretation of the results and wording of the manuscript. Rafael Tavares Jomar, Débora Cristina Leitão dos Santos and Tânia Cristina de Oliveira Valente contributed for critical review and wording of the article. All the authors approved the final version to be published.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interests to declare.

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