Original Article

Protocols for telephone follow-up of people with gastrointestinal cancer undergoing chemotherapy

Protocolos para acompanhamento por telefone de pessoas com neoplasia gastrointestinal em quimioterapia

Protocolos para el acompañamiento telefónico de personas con neoplasia gastrointestinal en quimioterapia

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Abstract

Objective: To describe the process of construction and validation of protocol content and appearance for telephone follow-up to reduce side effects (lack of appetite, nausea and vomiting, diarrhea and constipation) associated with outpatient antineoplastic chemotherapy for people with gastrointestinal malignancy.

Methods: This is a methodological and quantitative study, carried out from September to November 2020, in three stages: scoping review development, protocol construction and material assessment by experts. They were developed according to the Pasquali's psychometrics methodological framework. For content assessment, the Delphi technique was used in two rounds (Delphi I [16 judges] and Delphi II [12 judges]) and, those items with Content Validation Coefficient (CVC) were considered valid greater than 0.80 and consensus of more than 80.0% in the Delphi technique. Data were analyzed using descriptive and inferential statistics (Binominal test).

Results: All protocol requirements reached agreement among the judges above 80.0% as well as all items reached statistically significant levels of assessment. At the end of Delphi II, the four protocols were significantly valid (lack of appetite [CVC = 0.98]; nausea and vomiting [CVC = 0.99]; diarrhea [CVC = 0.99]; and constipation [CVC = 0.98]).

Conclusion: The content of the protocols demonstrated high credibility and their adoption in health institutions can contribute to telephone follow-up in reducing side effects (lack of appetite, nausea and vomiting, diarrhea and constipation) associated with outpatient antineoplastic chemotherapy for people with gastrointestinal malignancies.

Resumo

Objetivo: descrever o processo de construção e validação de conteúdo e aparência de protocolos para o acompanhamento por telefone na redução dos efeitos colaterais (inapetência, náusea e vômito, diarreia e constipação) associados à quimioterapia antineoplásica ambulatorial para pessoas com neoplasia maligna gastrointestinal.

Métodos: Estudo metodológico e quantitativo, realizado no período de setembro a novembro de 2020, em três etapas: realização de *scoping review*, construção dos protocolos e avaliação do material por especialistas. Foram desenvolvidos segundo o referencial metodológico da psicometria de Pasquali. Para avaliação de conteúdo, empregou-se a técnica de Delphi em duas rodadas (Delphi I [16 juízes] e Delphi II [12 juízes]) e, considerou-se válidos aqueles itens com Coeficiente de Validação de Conteúdo (CVC) maior que 0,80 e consenso de mais de 80,0% na técnica de Delphi. Os dados foram analisados por meio da estatística descritiva e inferencial (Teste binominal).

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Conflicts of interest: nothing to declare.

Resultados: Todos os requisitos dos protocolos alcançaram concordância entre os juízes superior a 80,0%, bem como todos os itens atingiram níveis de avaliação estatisticamente significativos. Ao final do Delphi II, os quatro protocolos se apresentaram expressivamente válidos (inapetência [CVC = 0,98]; náusea e vômito [CVC = 0,99]; diarreia [CVC = 0,99]; e, constipação [CVC = 0,98]).

Conclusão: O conteúdo dos protocolos demonstrou alta credibilidade e, sua adoção nas instituições de saúde, pode contribuir para o acompanhamento por telefone na redução dos efeitos colaterais (inapetência, náusea e vômito, diarreia e constipação) associados à quimioterapia antineoplásica ambulatorial para pessoas com neoplasia maligna gastrointestinal.

Resumen

Objetivo: Describir el proceso de construcción y validación de contenido y apariencia de protocolos para el acompañamiento por teléfono en la reducción de los efectos colaterales (inapetencia, náuseas y vómitos, diarrea y constipación) asociados a la quimioterapia antineoplásica ambulatoria para personas con neoplasia maligna gastrointestinal.

Métodos: Estudio metodológico y cuantitativo, realizado en el período de septiembre a noviembre de 2020, en tres etapas: realización de *scoping review*, construcción de los protocolos y evaluación del material por especialistas. Fueron desarrollados según el referente metodológico de la psicometría de Pasquali. Para la evaluación de contenido se utilizó la técnica de Delphi en dos rondas (Delphi I [16 jueces] y Delphi II [12 jueces]) y se consideraron válidos los ítems con Coeficiente de Validez de Contenido (CVC) superior a 0,80 y consenso superior al 80,0 % en la técnica de Delphi. Se analizaron los datos por medio da estadística descriptiva e inferencial (Prueba binominal).

Resultados: Todos los requisitos de los protocolos alcanzaron la coincidencia entre los jueces superior al 80,0 %, así como todos los ítems alcanzaron niveles de evaluación estadísticamente significantes. Al fin del Delphi II, los cuatro protocolos se mostraron expresivamente válidos (inapetencia [CVC = 0,98]; náuseas y vómitos [CVC = 0,99]; diarrea [CVC = 0,99]; y constipación [CVC = 0,98]).

Conclusión: El contenido de los protocolos demostró alta credibilidad y su adopción en las instituciones de salud, puede contribuir para el acompañamiento por teléfono en la reducción de los efectos colaterales (inapetencia, náuseas y vómitos, diarrea y constipación) asociados a la quimioterapia antineoplásica ambulatoria para personas con neoplasia maligna gastrointestinal.

Introduction

In the oncological context, there has been an increase in the use of outpatient treatments, which represent a different context from hospitalization. Compared to the hospital setting, outpatient antineoplastic chemotherapy (AC) results in better quality of life (QoL) and lower treatment costs for patients. However, administering outpatient AC is challenging due to high demand, time pressures, and low level of control. Also, side effects tend to occur at home.[1,2]

AC is a type of systemic treatment, consisting in the use of drugs that, alone or in association, act in the process of cell growth and division and,[1] systemic toxicities are prevalent and often little recognized, resulting in high rates of uncomfortable symptoms and, consequently, avoidable emergency room visits and hospitalizations.[1,3-6]

Outpatient care requires patients to manage symptoms in their home, however, on a regular basis, these people are inadequately prepared or forget instructions on how to deal with unrelieved symptoms.[7] As a result, the management of symptoms of malignant neoplasm is often unsatisfactory.[8,9]

Nursing care in oncology, based on good practices, requires the construction and implementation of an interconnected system of care protocols, which allows the realization of nursing actions based on scientific evidence, contributing to professional decision-making effectively, quickly and individually.[10,11]

It is noteworthy that telephone follow-up is a modality of care that allows interaction between health professionals and their patients.[1] The telephone intervention in the daily routine of nursing has been recommended as a significant aid to clinical practice, as it can provide important contributions to health promotion, as it enables the control of adverse effects, fast driving and support for therapeutic adherence.[12] In fact, telephone follow-up is an intervention established by the Nursing Interventions Classification (NIC), which allows monitoring a person's health conditions to act in circumstances of an abnormal state.[1,13] The relevance of this study is to provide protocols in order to substantially contribute to the provision of quality care.

This study aimed to describe the process of constructing and validating protocol content and appearance for telephone follow-up to reduce side effects (lack of appetite, nausea and vomiting, diarrhea, and constipation) associated with outpatient antineoplastic chemotherapy for people with gastrointestinal malignancies.

Methods

This is a methodological study, carried out from September to November 2020, based on the Pasquali's psychometrics methodological framework,[14] developed in three stages: scoping review, construction of protocols and content validation and appearance by judges/experts.

Initially, the results from a scoping review were used according to the international guide PRISMA-ScR recommendations[15] and in the method proposed by the Joanna Briggs Institute, Reviewers Manual 2020,[16] based on national and international scientific evidence (Appendix 1). The Common Terminology Criteria for Adverse Events (CTCAE) version 5,[17] produced by the North American National Cancer Institute (NCI), was also used; the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) and the Classification of Nursing Interventions (NIC) taxonomy.[13]

The scoping review protocol was registered in the Open Science Framework (https://doi.org/10.17605/OSF.IO/5S7DE). The participant, concept and context (PCC) strategy was used to construct the research question, in which: P (participants) - oncology nurse; C (concept) - telephone follow-up of patients with gastrointestinal malignancies; and C (context) – antineoplastic chemotherapy clinics. Thus, the established research question was: what scientific evidence, in the context of outpatient antineoplastic chemotherapy, is available for telephone follow-up of patients with gastrointestinal malignancies performed by nurses?

The search strategy was adapted according to each database's specificities, and the analogous combination of descriptors was preserved: ("Telemedicine"[Mesh] OR "Telenursing"[Mesh] OR "Telephone"[Mesh] OR "Telephone Consultation" (Iowa NIC) OR "Telehealth"[Mesh]) AND ("Oncology Nursing"[Mesh] OR "Nursing"[Mesh]) AND ("Anus Neoplasms"[Mesh] OR "Cecal Neoplasms"[Mesh] OR "Colonic Neoplasms"[Mesh] OR "Digestive System Neoplasms"[Mesh] OR "Duodenal Neoplasms"[Mesh] OR "Gastrointestinal Neoplasms"[Mesh] OR "Ileal Neoplasms"[Mesh] OR "Intestinal Neoplasms"[Mesh] OR "Jejunal Neoplasms"[Mesh] OR "Sigmoid Neoplasms "[Mesh] OR "Stomach Neoplasms "[Mesh] OR "Esophageal Neoplasms "[Mesh] OR "Colorectal Neoplasms"[Mesh]).

After selecting the descriptors and synonyms, an electronic search of the studies was carried out, from November 2019 to January 2021, in the PUBMED (National Library of Medicine and National Institutes of Health), CINAHL (Cumulative Index to Nursing and Allied Health Literature), Web of Science, Scopus, LILACS (Latin American and Caribbean Health Science Literature) and Cochrane Central Library databases.

Articles published in Portuguese, English or Spanish, with abstracts available in full in the selected databases, which addressed telephone follow-up by nurses with patients with gastrointestinal malignancies, from 2013 onwards were included. This time frame was justified due to the framework of the Brazilian National Policy for Cancer Prevention and Control in the Health Care Network for People with Chronic Diseases (*Política Nacional para a Prevenção e Controle do Câncer na Rede de Atenção à Saúde das Pessoas com Doenças Crônicas*) within the scope of the Unified Health System (*Sistema Único de Saúde*).[18] Studies that did not include the guiding question, editorials, experience reports, theoretical essays, a single case study and surveys that addressed telephone follow-up carried out by health professionals who were not nurses were excluded.

Studies were selected by two independent reviewers, with the goal of confirming their relevance to the scope review questions and, if so, the data of interest was extracted. Doubts or inconsistencies were resolved by consensus among the authors. For separating, summarizing and reporting the essential information found in each study, a structured instrument was used to collect these data, which allowed the synthesis, interpretation and analysis of the extent, nature and distribution of the studies incorporated in the review.[3]

In the process of elaborating the protocols, the construct was subdivided into four modalities (all containing a flowchart with a graphic algorithm

followed by detailed guidelines with nursing interventions/actions, in addition to a scientific foundation), namely: a) Protocol for telephone follow-up to reduce the inappetence of people with gastrointestinal malignancies undergoing outpatient antineoplastic treatment (PNMGTAA); b) Protocol for telephone follow-up to reduce nausea and vomiting of PNMGTAA; c) Protocol for telephone follow-up to reduce PNMGTAA diarrhea; d) Protocol for telephone follow-up to reduce PNMGTAA constipation.

It is noteworthy that the algorithms were developed according to Pimenta et al.'s proposal,[19] in which there is the use of graphic forms with certain meanings in the construct. They present an initial approach to patients over the telephone, in order to check the connection quality; description of drugs with high and moderate degree to cause the respective side effects of each protocol; questions related to the frequency, characteristics, period and management of inappetence, nausea and vomiting, diarrhea and constipation; guidance in cases of complications and/or worsening of symptoms related to outpatient AC.

Each of these protocols was assessed according to the criteria established by Pasquali:[14] behavior, objectivity, simplicity, clarity, relevance, accuracy, variety, modality, typicality, credibility, breadth and balance. It should be noted that there was a framework elucidating each of these 12 criteria and they were assessed using a Likert-type scale as follows: "1 - inadequate (I)", classified as disagreement degree; "2 - partially adequate (PA)"; "3 - adequate (A)", labeled as degree of agreement.

In the protocol validation stage, in order to reach the number of judges recommended by Pasquali,[14], i.e., six to 20 judges. This process was guided through the analysis of selected expertise for the research, through the appreciation of resumes in the CNPq's *Platforma Lattes*. For this purpose, the simple search form was used, in the field "search for", in the category "subject", through the use of the terms "oncology" and/or "chemotherapy" and/or "validation". A total of 389 doctors were identified.

For the screening of possible expertise, the Fehring model[20] was adapted and used (maximum score of 14 points), with a minimum score of five points being assigned: master's and doctorate in nursing or related fields (mandatory criterion); dissertation or thesis on oncology and/or validation (3 points); oncology experience of at least three years (3 points); certificate or title of expert in oncology nursing (2 points); research in oncology and/or validation in the last five years (2 points); authorship of at least two articles, in the last two years, in oncology (2 points); participation in a research group involving the theme Oncology and/or validation (2 points).[20]

After the search, the first 50 eligible judges were chosen. These received an invitation letter by email, with a period of up to 20 days to respond; in addition to the Informed Consent Form (ICF), with instructions to be able to analyze and assess the protocols. The instrument to be completed for validation was built in Google Docs, with participant characterization information, graphic algorithms and guidelines. After each protocol there was a space in which judges could provide suggestions for modification and improvement.

This process was conducted using the Delphi technique. In Delphi I, 16 experts participated, a stage in which there were suggestions for changing the protocols to improve them. After analyzing the Delphi I data and reformulating the protocols, as recommended by experts, they were contacted and sent a new electronic form with protocols adjusted for a new assessment (Delphi II), 12 judges participated. To fill out the form, the judge needed approximately 40 minutes and, after starting the validation process, it could not be discontinued.

For protocol assessment, experts' judgments were entered into a database in Microsoft Excel 2016®, and after being analyzed, the scores attributed to each protocol were verified. Protocol relevance was obtained by applying the CVC.[21] The item that presented more than 80% of agreement among judges (assessed as adequate) and a CVC>0.80.[22]

Nevertheless, a descriptive and inferential analysis (binomial test) was carried out. For this purpose, ρ-value$\leq$0.05 was adopted as a parameter for statistical significance.

The research was approved by the Institutional Review Board of the *Universidade Federal de São João*

del-Rei, under Opinion 2.010.532, and it is a subproject of an "umbrella" research entitled Collective construction of protocols and manuals.

It is noteworthy that the external validation of the protocols has not yet been carried out, since it is the elaboration of protocols that, only after their implementation, can be re-assessed and adjusted when necessary.

Results

For protocol construction, the changes made consisted of, essentially, in objectivity, simplicity, clarity, relevance, variety (language is adequate and allows content interactivity), modality (vocabulary is appropriate, without generating misunderstandings), and typicity (vocabulary is consistent with the theme, with adequate concepts). Each completed protocol had a flowchart with a graphic algorithm followed by detailed guidelines with nursing interventions (Appendix 2).

It is noteworthy that, in these protocols, patients who undergo AC with the potential for nausea, vomiting, diarrhea and constipation will need to be assessed by a nurse, by applying the CTCAE scale. Persons in the first AC cycle must have a record of the guidelines provided in accordance with the protocols. From the second AC cycle, it will be necessary to have a medical record, the guidelines provided/modified and patient adherence or not, with the respective reasons as well as any person's refusal to follow the guidelines.

In the validation process, the expert committee was composed of 16 professionals in the first round and 12 in the second (it is noteworthy that these 12 experts collaborated in both rounds), with the loss of four judges due to the non-return of the protocols within the term signed in advance. Doctors with care and management experience in oncology participated, in addition to teaching. Experts' minimum age was 35 years and the maximum was 58 (mean=40.12 and standard deviation=6.75 in Delphi I; mean=42.71 and standard deviation=7.80 in Delphi II), whose mean training time was 20.20 and standard deviation=5.81 in Delphi I; mean=19.64 and standard deviation=5.84 in Delphi II. They worked in four regions of Brazil, namely: southeast with 13 (81.1%) judges, northeast, center-west and south, with one (6.3%) expertise each.

Table 1 describes the final consensus among judges regarding the analyzed items of protocol content for telephone follow-up in the reduction of side effects (lack of appetite, nausea and vomiting, diarrhea and constipation) associated with AC for people with gastrointestinal cancer, who obtained agreement ("adequate"), according to Pasquali's assessment criteria.

Table 1. Consensus among judges in Delphi I and II stages for the items assessed of protocol content for telephone follow-up in the reduction of side effects (lack of appetite, nausea and vomiting, diarrhea and constipation) associated with outpatient chemotherapy for people with gastrointestinal cancer

Items	Reduction of side effects associated with chemotherapy							
	Inappetence		Nausea and vomiting		Diarrhea		Constipation	
	Delphi I (p-value*) n(%)	Delphi II (p-value*) n(%)	Delphi I (p-value*) n(%)	Delphi II (p-value*) n(%)	Delphi I (p-value*) n(%)	Delphi II (p-value*) n(%)	Delphi I (p-value*) n(%)	Delphi II (p-value) n(%)
Behavior	0.01(89.5)	0.00(100.0)	0.02(87.5)	0.00(100.0)	0.04(85.4)	0.00(100.0)	0.18(81.2)	0.00(100.0)
Objectivity	0.01(89.5)	0.00(100.0)	0.04(85.4)	0.00(100.0)	0.04(85.4)	0.00(100.0)	0.18(81.2)	0.00(100.0)
Simplicity	0.01(89.5)	0.00(100.0)	0.01(89.5)	0.00(100.0)	0.04(85.4)	0.00(100.0)	0.04(85.4)	0.00(100.0)
Clarity	0.01(89.5)	0.002(97.2)	0.02(87.5)	0.00(100.0)	0.07(83.3)	0.00(100.0)	0.30(79.1)	0.002(97.2)
Relevance/pertinence	0.01(89.5)	0.00(100.0)	0.01(89.5)	0.00(100.0)	0.04(85.4)	0.002(97.2)	0.04(85.4)	0.00(100.0)
Accuracy	0.04(85.4)	0.00(100.0)	0.02(87.5)	0.002(97.2)	0.02(87.5)	0.00(100.0)	0.30(79.1)	0.002(97.2)
Variety	0.01(89.5)	0.00(100.0)	0.01(89.5)	0.00(100.0)	0.02(87.5)	0.00(100.0)	0.02(87.5)	0.00(100.0)
Modality	0.01(89.5)	0.002(97.2)	0.01(89.5)	0.00(100.0)	0.003(91.6)	0.00(100.0)	0.07(83.3)	0.00(100.0)
Typicity	0.01(89.5)	0.00(100.0)	0.003(91.6)	0.00(100.0)	0.003(91.6)	0.00(100.0)	0.04(85.4)	0.00(100.0)
Credibility	0.01(89.5)	0.00(100.0)	0.01(89.5)	0.00(100.0)	0.02(87.5)	0.00(100.0)	0.02(87.5)	0.00(100.0)
Breadth	0.003(91.6)	0.00(100.0)	0.003(91.6)	0.00(100.0)	0.04(85.4)	0.00(100.0)	0.04(85.4)	0.00(100.0)
Balance	0.00(100.0)	0.00(100.0)	0.01(89.5)	0.00(100.0)	0.01(89.5)	0.00(100.0)	0.02(87.5)	0.00(100.0)

*p-value referring to the Binominal test (significant for p-values<0.05)

According to what was exposed in Table 1, it was observed that the care protocols inappetence, nausea and vomiting and diarrhea were within the recommended breadth to be considered valid from the Delphi I stage. Regarding constipation, they were below of the recommended, for the protocol to be considered valid in Delphi I, the items clarity (79.1%) and accuracy (79.1%). It is noteworthy that the items mentioned above did not show statistical significance in the agreement among judges. It should be noted that judges' suggestions in the first round (Delphi I) for the items that needed to be revised were regarding their form of presentation, inclusion, exclusion, relocation or division (Include Bristol Scale, standardize algorithm wording, review wording, remove action, manually remove fecal impaction, if necessary, as recommended by the Federal Council of Nursing; this action can be performed by nurses as long as it is registered in an institutional protocol).

In the flowchart, with the graphic algorithm and care guidelines for AC-induced inappetence, for telephone follow-up to reduce the side effect of inappetence related to AC for people with gastrointestinal cancer, content was clearly, unequivocally and relevantly explained (boxes were separated about lack of appetite and other symptoms; writing has been revised; there was an improvement in relation to colors and an increase in the size of the font used; guidelines for professionals and patients were included; guidelines were included regarding the use of non-abrasive toothpaste and mouthwashes with 0.9% saline solution or 3% carbonated water four to six times a day; content that was not exclusive to inappetence was removed).

In the care protocol for telephone follow-up to reduce nausea and vomiting associated with AC for people with gastrointestinal cancer, judges' suggestions were regarding its form of presentation, inclusion of instructions and relocation (high and moderate drugs were changed emetogenic degree for treatment protocols with high and moderate emetogenic degree; questions were included that assess the risk of dehydration; actions were oriented to patients and/or family members were separated from exclusive actions of nurses; and content wording was revised).

Regarding the care protocol for telephone follow-up of AC-induced diarrhea for PNMGTAA, judges' recommendations allowed the desired goal to be reached. The Bristol Scale was added, guidance for after evacuation, washing the region with soap and water and drying with a soft towel, without friction, and scientific basis. This last item was added to all care protocols.

In the Delphi II round, all requirements showed agreement above 80.0% and were statistically significant ($\rho \leq 0.05$), which corresponds to agreement among judges. In addition, after judges' suggestions (Delphi II), modifications were essential only in relation to the color of algorithms' graphic forms, in order to make them more prominent and differentiated in the care protocols. It is noteworthy that, at the end of Delphi II, the care protocols were valid (lack of appetite [CVC = 0.98]; nausea and vomiting [CVC = 0.99]; diarrhea [CVC = 0.99]; and constipation [CVC = 0.98]).

Finally, there was no objection from the judges regarding the recommendation for the use of care protocols in clinics where AC is administered. In Delphi II, 100.0% made the recommendation without the need for changes.

Discussion

AC offers great benefit to people with malignant neoplasms. In general, therapeutic and toxic doses are very close, and[4,7] is associated with a myriad of symptoms and side effects from treatment that can range from mild to potentially fatal, severe and disabling.[6]

Therefore, early recognition and effective management of these symptoms by health professionals, patients and family members are essential to reduce the sequelae of physical and psychological treatment. However, most patients receive AC in an outpatient setting and are therefore compelled to manage side effects at home without direct support from cancer health professionals. Thus, the use of

home telephone follow-up can be a key factor in cost-effective health care.[6,7]

The care protocols, from two Delphi stages, were considered valid in their content (lack of appetite [CVC = 0.98]; nausea and vomiting [CVC = 0.99]; diarrhea [CVC = 0.99]; and constipation [CVC = 0.98]), are acceptable to consider valid. Therefore, the protocols proved to be valid; and its application can contribute to health promotion, as it is a tool that aims to improve the quality of care, reduce adverse events, support therapeutic adherence and improve communication between patients and nurses. It involved the participation of 16 judges in Delphi I (DI) and 12 in Delphi II (DII) stages, with a view to making the care protocols reliable and valid with regard to content and appearance. Validity is an essential criterion for validating the quality of an instrument.[11,21,22]

As for preeminence of females (87.5% - DI and 83.5% - DII) among the judges participating in this research, a study[23] showed that this fact has followed the profession since the beginnings of nursing history, since it is one of the feminized health professions and maintains the relationship between "care" and "feminine action". Around 85.0% of nursing professionals are women.[23,24]

The experience of the judges participating in the assessment phases stands out, who were doctors with extensive experience in cancer care, management, research and teaching. From this angle, literature shows that holders of masters' and PhD degrees are the main responsible for enabling repercussions on practices and, consequently, on the advancement of nursing.[11,25]

Therefore, it is understood that the participation of experienced professionals involved in cancer care, management, research and teaching is vehemently relevant for the validation of protocols to be applied in practice, as this study proposed when validating assistance protocols for telephone follow-up assistance in reducing the side effects associated with AC.

In the validation process of care protocols, the final product of this research, the judges presented a significant coefficient of agreement in all items assessed, in order to make the instrument valid in relation to the assessment of usefulness/relevance, objectivity, simplicity, clarity, relevance, accuracy, variety, consistency, feasibility, updating, accuracy, and behavior.[14] This certifies that the instrument is suitable for a reliable practical applicability.

With regard to CVC, it can be inferred that there was a consensus among participants in the care protocol validity judgement, as well as it was considered that the assessed instrument supplies content for telephone follow-up in the reduction of side effects (lack of appetite, nausea and vomiting, diarrhea and constipation) associated with outpatient AC for people with gastrointestinal malignant neoplasm. This reality is proven by the agreement obtained among judges in the assessment of inappetence (CVC: DI - 0.90 and DII - 0.98), nausea and vomiting (CVI: DI - 0.89 and DII - 0, 99), diarrhea (CVI: DI – 0.87 and DII – 0.99), and constipation (CVI: DI – 0.84 and DII – 0.98). They were statistically significant ($\rho \leq 0.05$), which denotes the achievement of better consensus associated with improvements in the protocols between Delphi rounds.

Despite the rigor in assessing content and appearance of care protocols, it is necessary to proceed with the consecutive phases, for operational and measurement equivalence. Therefore, its application was started in a large Brazilian hospital, qualified as a High Complexity Oncology Care Unit (UNACON - *Unidade de Assistência de Alta Complexidade em Oncologia*) so that it is possible to verify its efficiency.

The limitation of this study is related to the specificity of the protocols for telephone follow-up in reducing only the side effects of inappetence, nausea and vomiting, diarrhea and constipation associated with outpatient AC for people with gastrointestinal malignancies. Therefore, it is recommended that further research be carried out for the construction and validation of protocols aimed at other side effects.

Even so, this research will contribute substantially to raising professionals' attention regarding the importance of adjustments to provide outpatient care with greater interaction between health professionals and patients, in addition to enabling

the control of some adverse effects, through telephone monitoring based on scientific evidence.

Conclusion

The validation process of care protocols enrolled 16 judges in Delphi I, who judged that only the items related to the constipation side effect were not adequate in terms of clarity (79.1%) and accuracy (79.1%), even so a CVC of 0.84 was obtained. In the second Delphi round, 12 judges were included, and the validation of protocol content and appearance was achieved (lack of appetite [CVC = 0.98]; nausea and vomiting [CVC = 0.99]; diarrhea [CVC = 0.99]; and constipation [CVC = 0.98]). Based on the results, it was proven that the protocols are reliable and valid in terms of content and appearance to be submitted to clinical validation in the practice of outpatient services.

Collaborations

Dias CM, Oliveira PP, Schlosser TCM, Martins QCS, Alves JMM, Souza RS, Silveira EAAS, Rodrigues AB, declare that they contributed to project design, data interpretation, relevant critical review of intellectual content and approval of the final version to be published.

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Appendix 1. References used as a foundation for protocol construction

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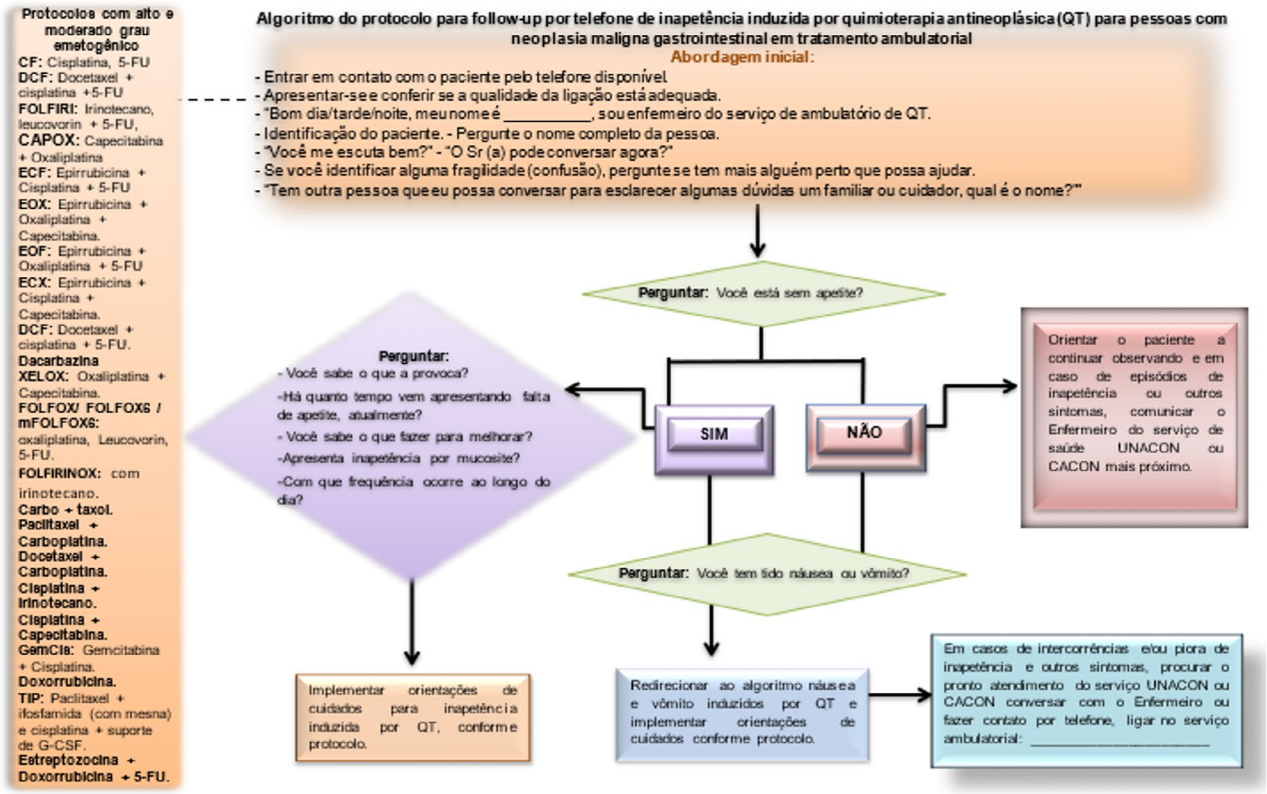
Appendix 2. Protocols with the respective graphic algorithm followed by detailed guidelines with nursing interventions



Orientações - Inapetência Induzida Por Quimioterapia Antineoplásica

- Verificar adesão ao tratamento (comparece em todas as sessões de QT? Segue as recomendações?);
- Avaliar crenças e conhecimentos a respeito de inapetência;
- Avaliar se há conhecimento sobre avaliação de risco de desidratação.

Orientar o paciente a:

- Identificar as preferências alimentares, se apresentar resistência por sentir gosto metálico, comer o que tolerar;
- Alimentar pelo menos 3 vezes ao dia e repousar após as refeições;
- Não ingerir líquidos junto com as refeições para não se sentir saciado;
- Dar preferência a alimentos líquidos ou pastosos, caso relate dificuldade em ingerir alimentos sólidos;
- Verificar a presença de xerostomia, se sim, orientar a beber líquidos em pequenas quantidades e várias vezes ao dia. Molhos, caldos e sopas nas refeições facilitam a mastigação e o ato de engolir. Fale sobre a saliva artificial, se for o caso;
- Dar preferência a alimentos mornos, evitar alimentos gelados ou quentes, caso o paciente relatar perda do paladar;
- Praticar exercícios leves, como caminhadas curtas, cerca de uma hora antes das refeições, caso não tenha nenhuma contraindicação;
- Pesar sempre que possível e comunicar se emagrecimento ao apoio nutricional do serviço de saúde.

Em caso de inapetência por mucosite induzida por quimioterapia antineoplásica, orientar o paciente a:

- Instituir uma rotina de escovação dos dentes utilizando escova estreita, de cerdas macias;
- Fazer a escovação delicada da língua (somente para prevenção, ou seja, quando não tem mucosite instalada);
- Usar o fio dental sempre que possível (dependerá de resultado de hemograma e avaliação da mucosa oral em última consulta);
- Usar creme dental não abrasivo, preferencialmente com bicarbonato de sódio e/ou flúor;
- Realizar a escovação após as refeições e antes de se deitar;
- Retirar as próteses dentárias e higienizá-las 30 minutos após as refeições e à noite;
- Suspender o uso de próteses dentárias (caso existam) se houver lesões na mucosa oral;
- Enrolar o dedo em uma gaze para a higienização, caso o cliente tenha dor e não consiga realizar escovação;
- Realizar bochechos com solução salina 0,9% ou água bicarbonatada a 3% de 4 a 6 vezes por dia (orientar o paciente a retirar os insumos para realização deste cuidado na instituição à qual está vinculado, caso não possua recursos para adquiri-los);
- Ingerir alimentos frios ou a temperatura ambiente, incluindo gelatinas e sorvetes de frutas que não sejam ácidas;
- Evitar alimentos que irritam a mucosa oral como os sucos cítricos alimentos picantes ou muito salgados, e ásperos e secos;
- Optar por alimentos fáceis de mastigar e engolir, em forma de purês e cremes, incluindo frutas macias e ricas em líquidos);
- Aumentar a ingestão de líquidos, bem como o teor de líquido dos alimentos, adicionando molho de carne, caldo de carne, ou molhos não picantes;
- Comunicar intercorrências para o enfermeiro solicitar o acompanhamento com nutricionista, com o respectivo registro de avaliação de mucosite, se atestando a incapacidade de alimentação e hidratação por via oral, o enfermeiro e/ou nutricionista irá contatar o médico sobre a situação do cliente e requerer avaliação para possível instalação de sonda nasoenteral.

Fundamentação Científica:

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Protocolos com alto e moderado grau emetogênico

CF: Cisplatina + 5-FU
DCF: Docetaxel + cisplatina + 5-FU
FOLFIRI: Irinotecano + Leucovorin + 5-FU
Capecitabina + Oxaliplatina
ECF: Epirrubicina + Cisplatina + 5-FU
EOX: Epirrubicina + Oxaliplatina + Capecitabina.
EOF: Epirrubicina + Oxaliplatina + 5-FU
ECX: Epirrubicina + Cisplatina + Capecitabina
DCF: Docetaxel + cisplatina + 5-FU
Dacarbazina
XELOX: Oxaliplatina + Capecitabina.
FOLFOX/ FOLFOX6 / mFOLFOX6: oxaliplatina + Leucovorin + 5-FU
Carbo + taxol
Paclitaxel + Carboplatina
Docetaxel + Carboplatina
Cisplatina + Irinotecano
Cisplatina + Capecitabina
GemCis: Gemcitabina + Cisplatina
Doxorrubicina
Estreptozocina + Doxorrubicina
Estreptozocina + Doxorrubicina + 5-FU
TIP: Paclitaxel + ifosfamida (com mesna) + ecisplatina + suporte de G-CSF

Algoritmo do protocolo para follow-up por telefone de náusea e vômito induzidos por QT para pessoas com neoplasia maligna gastrointestinal em tratamento ambulatorial

Abordagem inicial:

- Entrar em contato com o paciente pelo telefone disponível.
- Apresentar-se e conferir se a qualidade da ligação está adequada
- "Bom dia/tarde/noite, meu nome é _____, sou enfermeiro do serviço de ambulatório de quimioterapia
- Identificação do paciente - Pergunte o nome completo da pessoa.
- "Você me escuta bem?" - "O Sr (a) pode conversar agora?"
- Se você identificar alguma fragilidade (dificuldade na fala, confusão), pergunte se tem mais alguém por perto que possa ajudar
- "Tem outra pessoa que eu possa conversar para esclarecer algumas dúvidas, um familiar ou cuidador, qual é o nome?"

Perguntar: Você sente náuseas?

SIM

NÃO

Perguntar:
-O episódio de vômito acontece antes da QT?
-Há quanto tempo vem apresentando náusea ou vômito?
-A náusea ou vômito iniciou atualmente?
-Você sabe o que provoca náusea ou vômito? Sabe o que melhora?
-Qual o aspecto do vômito?
-Com que frequência você tem as náusea ou vômito ao longo do dia?
-Qual a quantidade de vômito?

Orientar o paciente a continuar observando e em caso de episódios de náusea e de vômitos, comunicar ao Enfermeiro do serviço de saúde UNACON ou CACON mais próximo.

Perguntar: Você tem tido vômitos?

Implementar orientações de cuidados para náusea e vômito induzida por QT, conforme protocolo.

Em casos de intercorrências e/ou piora da náusea e do vômito, procurar o pronto atendimento conversar com o enfermeiro e/ou médico do serviço de saúde CACON ou UNACON ou faça contato por telefone, ligue no serviço ambulatorial: _____

Orientações - Náuseas e Vômitos Induzidos Por Quimioterapia Antineoplásica

- Verificar adesão ao tratamento (seguimento das recomendações, adesão aos antieméticos prescritos pelo médico);

- Avaliar crenças e conhecimentos a respeito das náuseas e vômitos;

- Verificar se existem fatores desencadeantes ou agravantes das náuseas e vômitos;

- Verificar se há conhecimento sobre avaliação de risco de desidratação (se não houver conhecimento, orientar a seguir as recomendações descritas no protocolo e procurar o serviço de saúde mais próximo para conversar com o enfermeiro responsável);

- Verificar se há auxílio para o paciente a identificar os fatores ambientais que aumentam náuseas e orientar o paciente sobre o manejo adequado dos fatores ambientais que intensificam a náusea, tendo em vista sua minimização e/ou controle (odores, estimulação visual, sons desagradáveis);

Orientar o paciente a:

- Realizar higiene bucal antes da refeição;
- Consumir quantidades pequenas de alimentos;
- Evitar frituras e doces;
- Consumir quantidades pequenas de alimentos;
- Planejar horários das refeições, dar preferência para alimentos em temperatura ambiente ou fria (picolé, sucos, chupar gelo);
- Evitar a ingestão de líquidos junto com as refeições;
- Evitar a ingestão de alimentos preferidos no dia da quimioterapia a fim de evitar que haja um bloqueio pelo alimento posteriormente;
- Inclinar-se ou apoiar a cabeça em caso de vômito (se necessário);
- Fazer a limpeza da boca e nariz após o episódio do vômito;
- Manter via aérea permeável; prevenir risco de aspiração (mantendo cabeceira elevada);
- Aguardar, pelo menos, 30 minutos após o episódio de vômito antes de ingerir líquidos e administrar medicamento para controle conforme prescrição médica (próprio paciente ou o cuidador);
- Repousar pelo menos 30 minutos após vômito;
- Monitorar frequência e quantidade e registrar (próprio paciente ou o cuidador);
- Observar o turgor da pele, fazendo uma prega com os dedos polegar e indicador e comunicar se retorno da pele está lento (tempo recomendado de 3 segundos);
- Pesar diariamente em jejum e anotar valor se tiverem balança em domicílio, ou realizar a pesagem no serviço de saúde disponível quando possível (posto de saúde, farmácias, ambulatório de quimioterapia), podendo ser executado por paciente, cuidador ou profissional de saúde e comunicar ao Enfermeiro se houver perda de peso e, este encaminhará ao nutricionista.

Fundamentação Científica:

Bubalo JS, Herrington JD, Takemoto M, Willman P, Edwards MS, et al. Phase II open label pilot trial of aprepitant and palonosetron for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients receiving moderately emetogenic FOLFOX chemotherapy for the treatment of colorectal cancer. Support Care Cancer. 2018 Apr;26(4):1273-9.
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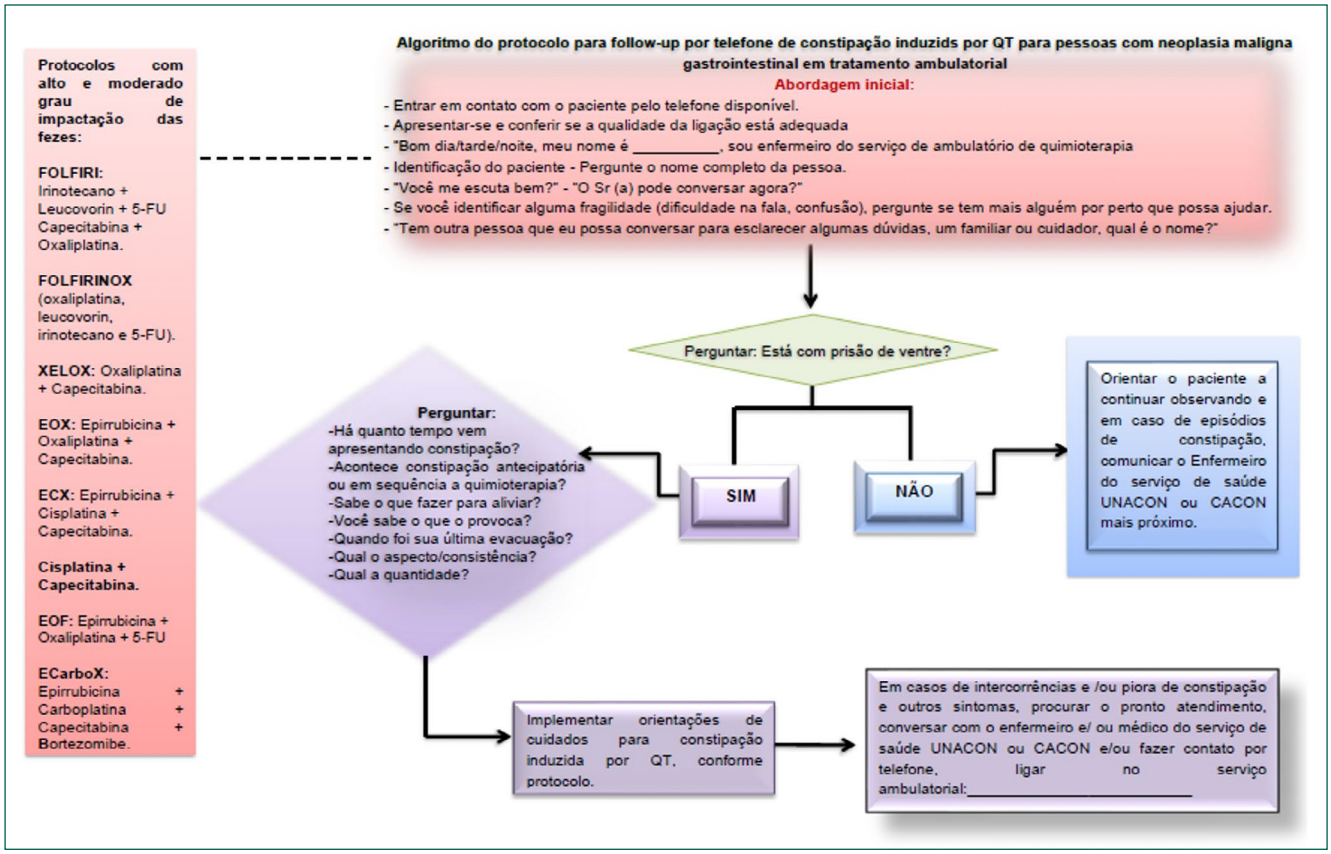

Orientações - Constipação Induzida Por Quimioterapia Antineoplásica

- Verificar adesão ao tratamento (comparece em todas as sessões de QT? Segue as recomendações?);
- Avaliar crenças e conhecimentos a respeito de Constipação;
- Verificar se existem fatores desencadeantes ou agravantes da constipação;
- Confirmar se o médico prescreveu analgésicos opioides e/ou laxantes para prevenção e alívio de sintomas;
- Pedir ao paciente ou o cuidador que classifique as fezes, segundo a consistência seguindo a Escala de Bristol (Martinez, Azevedo 2012):
  - Tipo 1: pequenas bolinhas duras separadas (como coquinho), difícil para sair;
  - Tipo 2: formato de linguiça encaroçada, com pequenas bolinhas grudadas;
  - Tipo 3: formato de linguiça com rachaduras na superfície;
  - Tipo 4: alongada com formato de salsicha ou cobra, lisa e macia;
  - Tipo 5: pedaços macios e separados, com borda bem definida, fáceis de sair;
  - Tipo 6: massa pastosa e fofa, com bordas irregulares;
  - Tipo 7: totalmente líquidas, sem pedaços sólidos.

Orientar ao paciente a:

- Optar por uma dieta com elevado teor de fibras (ex: laranja, couve);
- Aumentar a ingestão de líquidos;
- Praticar e tentar manter um diário alimentar;
- Realizar limpeza seguida com água e sabão do vaso sanitário, sempre dando descargas (fazer o uso de máscara e luvas) devidas eliminação de toxicinas do quimioterápico;
- Observar a consistência das fezes e quantidade;
- Comunicar com o enfermeiro se houver flatulência, aumento na frequência ou intensidade dos sons intestinais distensão abdominal, dor;
- Ingerir de forma apropriada o medicamento analgésico e/ou laxante, conforme prescrição médica quando apresentar sintomas de dor, flatulência, distensão abdominal;
- Pesar com regularidade quando possível e anotar (se balança em domicílio, ou em farmácias, posto de saúde ou ambulatório de quimioterapia) e comunicar o enfermeiro se houver ganho de peso e encaminhará ao nutricionista para avaliação e;
- Explicar ao paciente que medicamentos opioides (ex: tramadol, morfina) e antieméticos (ex: Ondasetrona) podem causar constipação.

Fundamentação Científica:

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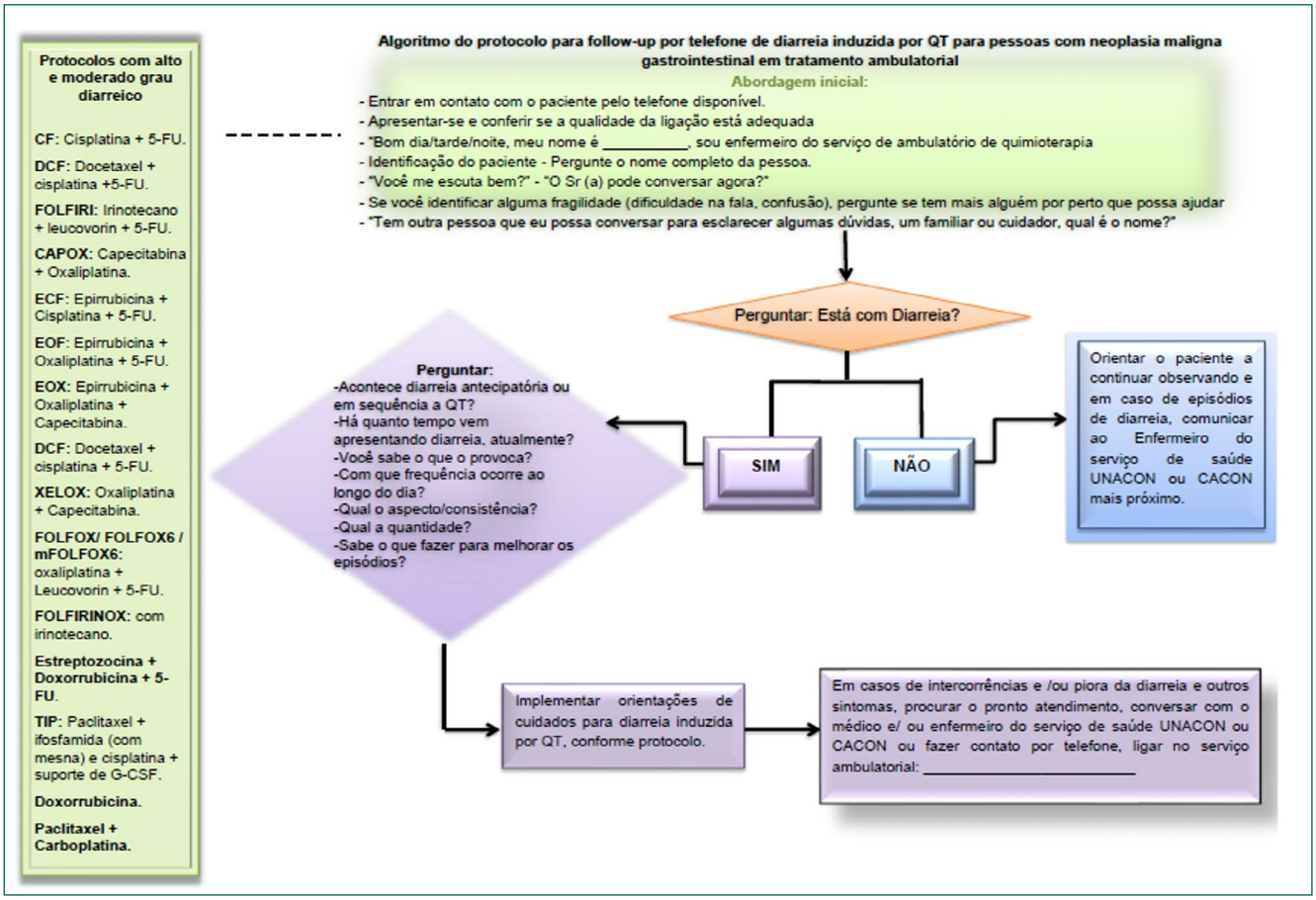

Orientações - Diarreia Induzida Por Quimioterapia Antineoplásica

- Verificar adesão ao tratamento (comparece em todas as sessões de QT, segue as recomendações corretamente);
- Avaliar crenças e conhecimentos a respeito da Diarreia;
- Verificar se existem fatores desencadeantes ou agravantes das diarreias;
- Verificar se há conhecimento sobre avaliação de risco de desidratação (se não houver conhecimento, orientar a seguir as recomendações descritas no protocolo e procurar o serviço de saúde mais próximo para conversar com o enfermeiro responsável);
- Pedir ao paciente ou o cuidador que classifique as fezes, segundo a consistência seguindo a Escala de Bristol (Martine; Azevedo, 2012):
  - Tipo 1: pequenas bolinhas duras separadas (como coquinho), difícil para sair;
  - Tipo 2: formato de linguiça encaroçada, com pequenas bolinhas grudadas;
  - Tipo 3: formato de linguiça com rachaduras na superfície;
  - Tipo 4: alongada com formato de salsicha ou cobra, lisa e macia;
  - Tipo 5: pedaços macios e separados, com borda bem definida, fáceis de sair;
  - Tipo 6: massa pastosa e fofa, com bordas irregulares;
  - Tipo 7: totalmente líquidas, sem pedaços sólidos
- Orientar o paciente a:
  - Monitorar o preparo seguro dos alimentos (se estão bem lavados, dentro do prazo de validade);
  - Tentar eliminar alimentos com lactose;
  - Evitar alimentos gordurosos e doces, alimentar mais proteína e calórico conforme apropriado (batata, arroz, maçã sem casca, banana-maçã, melancia) e dieta com baixo teor de fibras (leite, cenoura); alimentos formadores de gases e muito temperados (repolho, molhos com pimenta);
  - Não ingerir água junto com as refeições, monitorar ingesta líquida;
  - Realizar limpeza seguida com água e sabão do vaso sanitário, sempre dando descargas (fazer o uso de máscara e luvas) devidas eliminação de toxinas do quimioterápico;
  - Lavar a região anal com água e sabão após a evacuação, observar a consistência das fezes e quantidade, se há presença dos sons intestinais audíveis (comunicar a frequência ao enfermeiro por telefone);
  - Ingerir medicamentos antidiarreicos, conforme prescrição médica;
  - Observar Xerodermia (o turgor da pele, fazendo uma prega com os dedos polegar e indicador e comunicar se retorno da pele está lento maior que 03 segundos, ressecado), observar Xerostomia (boca seca);
  - Pesar com regularidade quando possível e anotar (se balança em domicílio, ou em farmácias, posto de saúde ou ambulatório de quimioterapia), comunicar o enfermeiro se perda de peso para encaminhar ao nutricionista.

Fundamentação Científica:

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