VALIDATION OF CHARACTERIZATION INSTRUMENT FOR PATIENTS WITH COLORECTAL PATHOLOGIES

Natalia Michelato Silva¹, Sara Rodrigues Rosado², Manoel Antônio dos Santos³, Helena Megumi Sonobe⁴

ABSTRACT

Objective: to validate an instrument for socio-demographic, clinical and therapeutic characterization of patients with chronic colorectal diseases. Method: this is a quantitative study of the content validation of an instrument by the psychometric method based on an integrative review. The Percentage of Concordance and the Content Validity Index (CVI) were used for content validation. Results: it was verified that the result of the application of the Concordance Percentage among the judges was superior to the recommended of 80%, especially in the evaluation of the pertinence to the proposed theme, whose agreement percentage was 100%. Conclusion: the instrument is representative of the content on the socio-demographic, clinical and therapeutic characteristics of patients with chronic colorectal diseases, divided into four sessions (personal information, social profile, health condition and medical record data) with 28 items, for full representation of the data of the study population. Descriptors: Ostomy; Colostomy; Colorectal Neoplasms; Medical Psychology; Interdisciplinary Studies; Validation Studies.

RESUMO

Objetivo: validar instrumento de caracterização sociodemográfica, clínica e terapêutica de pacientes com patologias colorretais crônicas. Método: trata-se de um estudo quantitativo de validação de conteúdo de um instrumento pelo método psicométrico com base em uma revisão integrativa. Utilizou-se o Percentual de Concordância e o Índice de Validade de Conteúdo (IVC) para validação de conteúdo. Resultados: verificou-se que o resultado da aplicação do Percentual de Concordância entre os juízes foi superior ao recomendado de 80%, com destaque na avaliação de pertinência ao tema proposto cujo percentual de concordância foi de 100%. Conclusão: conclui-se que o instrumento é representativo do conteúdo sobre as características sociodemográficas, clínicas e terapêuticas de pacientes com patologias colorretais crônicas, sendo dividido em quatro sessões (informações pessoais, perfil social, condição de saúde e dados do prontuário médico) com 28 itens, para representação plena dos dados da população estudada. Descriptores: Ostomia; Colostomia; Neoplasias Colorretais; Psicologia Médica; Pesquisa Interdisciplinar; Estudos deValidação.
INTRODUCTION

The change in the morbidity and mortality profile of the population currently characterized by the prevalence of chronic noncommunicable diseases due to the increase in life expectancy, modernization with industrialization and the effects of urbanization are contextualized.\(^1\)\(^2\)

Among the CNCDs, cancer is the predominant disease, with colorectal cancer (CRC) as the second type that most affects the Brazilian population. In 2016/2017, 15,070 new cases in men and 17,530 in women were estimated.\(^3\) Despite the prevalence in people over 60 years old, a study was developed in the United States that indicated an increase in incidence among young people aged 20-29 years old, which doubled since 1980. Among the possible factors that influenced this change, there is the increase in the consumption of processed foods (bacon, ham, hot dog, sausage, mortadella, among others) and low intake of dietary fiber, as well as genetic aspects, a predominance of sedentary lifestyle, obesity and lifestyle habits, which influenced this change such as smoking and alcoholism.\(^4\)

The therapeutic indication, the location and staging of the tumor is directly related to the early diagnosis for the CRC. Radiation therapy, antineoplastic chemotherapy and oncological surgery, either alone or in combination, are presented as treatment goals.\(^5\)

Other chronic colorectal diseases such as inflammatory bowel diseases (IBD) whose preventive and risk aspects are similar and potentiate the development of CRC, are also highlighted. Among these, Crohn's disease (CD) has an increased incidence in the population.\(^6\)

There is the possibility of making a temporary or definitive intestinal stoma through the surgical treatment. The stoma for fecal elimination results from the need for exteriorization of the ileum or large intestine, called as ileostomy and colostomy.\(^7\)

Physical and psychosocial changes for patients and their families are associated with the development of intestinal stoma, as it is associated with various feelings such as fear, insecurity, mutilation and suffering. These can be self-destructive because they lead to existential conflicts, which can result in psychological, emotional and social changes, in addition to work, leisure and sexuality.\(^8\)

The physical and psychic suffering caused by the stoma is smoothed through better rehabilitation, with the assistance of an interdisciplinary and specialized team, consisting of surgeon, nurse, psychologist, nutritionist and social worker, to the patient and his family in the perioperative period. Also, care from hospital stay, with perioperative procedural and psychosocial care, self-care teaching, family preparation for home care, and specific psychological support for this period.

To characterize this population, with regard to sociodemographic, clinical and therapeutic aspects, it is fundamental to elaborate an instrument that identifies these characteristics and allows their analysis. For this elaboration, it is necessary to carry out an integrative review to analyze the studies on this subject, with identification of the necessary data to characterize this population, as well as the information primordial to carry out a research with this patients.

Therefore, it is necessary to carry out an integrative review as a strategy to base the elaboration of the instrument, aiming at the analysis and synthesis of researches, which contributed to the decision making, deepening of the theme and improvement of clinical practice.\(^9\)

Therefore, it is necessary to build and validate specific instruments for a given population as an effective tool, with a discussion of contents and constructs with health professionals applicable in daily clinical practice.

It is known that to carry out a validation of a research instrument, it is necessary to focus its content to allow the analysis and evaluation for the adequacy of the instrument.\(^10\)

There is a shortage in the literature of validated instruments on the subject, mainly for the characterization of stoma, so it becomes fundamental as a contribution in the promotion of scientific information and development.

objetivo

- To validate the socio-demographic, clinical and therapeutic characterization of patients with chronic colorectal diseases.

METHOD

This is a quantitative approach, of content validation type, of an instrument to characterize patients with chronic colorectal diseases in their sociodemographic, clinical and therapeutic aspects.
An integrative review was carried out in the databases (PubMed, Cinahl, PsycINFO and WOS) and the Scielo journal portal. For the construction of the instrument structure (formulation of the questions and their quantity), the psychometric theory of instrument construction was used.\(^9\)

Subsequently, a content validation was performed by the Percentage of Concordance between the judges and the Content Validity Index (CVI). This validation aims to judge the adequacy of the instrument for the object of study. For this, it is necessary that judges considered specialists in the subject evaluate the instrument on the representativity and relevance of the content items to obtain information about these patients.\(^11\)

It is recommended that the number of judges be at least five and maximum of ten experts.\(^12\) For the selection of these experts, the criteria were established according to Fehring Validation Model: to have experience in the area; be a scholar and have carried out studies on the subject; participate in research groups, projects and events that approach the subject, besides obtaining adequate knowledge about the physical and psychosocial aspects that encompass this population. Therefore, the criteria that define a professional's expertise can be adapted considering the thematic and the objective involved, with clarity and justifications.

The instrument was judged according to the criteria: Appearance: attributed to the aspect, form and exteriority of the form; Clarity/understanding: a relationship between transparency, perceptibility and comprehensibility of data is indicated; Content: refers to the content contained in each item; Efficiency/Consistency: refers to the production of a desired effect or a good result associated with the reality, veracity and firmness of the data; Objectivity: it is attributed to the observation of the question, capable of understanding, without mixing personal ideas; and Validity to the proposed model: refers to the adaptation and appropriation of the instrument through the integrative review.\(^14\)

The evaluations were sent to the judges by electronic correspondence, containing the instructions for their realization. Only one of the options between “Adequate”, “Needing Adequacy” and “Inadequate” (modified on a Likert scale) was allowed for each item of evaluation of the instrument. There was also a space for comments and suggestions at the end of the instrument.\(^11\)

Values were assigned for the validation response options between 0 and 2, with 0 for the “Appropriate” item, 1 for “Needing Adequacy” and 2 for “Inadequate” items. The Concordance Percentage was used to analyze the validity of the content, whose minimum concordance percentage among the judges should be 80% to be considered satisfactory.\(^11\)

The Content Validity Index (CVI) was also applied to measure the proportion or percentage of agreement among the judges on the items. To calculate the VCI, the formula described by Tilden et al.\(^15\) was used: \(CVI = \frac{\text{number of answers 1 or 2}}{\text{total number of answers}}\). It is evidenced that the recommended value for each item to be considered validated should be higher than 0.78.\(^16\)

It should be noted that the collection of information only occurred after the approval of the Ethics Committee of the University of São Paulo at Ribeirão Preto College of Nursing, protocol number 583564162.0000.5393.

### RESULTS

The instrument was divided into four sessions: personal information (six items); social profile (eight items); health condition (four items); and medical records data (ten items), totaling 28 items.

The characterization of the profile of the judges, age, profession, professional training and clinical experience with patients with chronic colorectal diseases was evidenced. Table 1 shows the distribution of judges according to these aspects.
The average age of the judges was 31.2 years old, all of them from the health area working with intestinal stomata patients, and most of them were nurses, all with professional training beyond graduation, having a Ph.D. and two with doctorate course in progress, with an average time of experience of 8.6 years. Thus, the criteria were established according to recommendations of Melo et al.\textsuperscript{13} for the selection of judges, favoring the obtaining of judges with relevant clinical experience for the validation of content.

Table 2 was used to describe the results of the pertinence of the sections contained in the instrument.

Each item of the sections that were classified according to the level of adequacy was evaluated. Also, pertinent suggestions were made in the sections that they thought necessary.

The items were evaluated by the VCI individually and grouped into six sections according to the proposed instrument (Table 3).

Note that the results of the VCI calculation showed a value of 1 for all sections of the instrument, always above 0.78, as recommended by the literature.

**DISCUSSION**

A validated instrument is needed for sociodemographic, clinical and therapeutic characterization for specific populations to obtain relevant information, paying attention to more appropriate interdisciplinary interventions that meet their real needs and demands.\textsuperscript{17}

It is relevant to know the sociodemographic, clinical and therapeutic characteristics of intestinal stomatal patients, since age, color, and lifestyle, especially FOR food and family history, are risk factors for the development of pathologies intestinal chronicles, and these data favor further investigation of this disease. Information on age is relevant, since colorectal cancer predominates in people over 60 years old; in relation to sex, predominates in women; high-fat foods, processed meats, processed products and low fiber intake are risk factors, as well as genetic aspects. The need for preventive interventions is emphasized when the diagnosis involves a hereditary component.\textsuperscript{18}

In the psychological aspects, it is important to investigate the patient's knowledge about their illness and treatments, with identification of individual and contextual characteristics related to the experience of illness and therapeutics, as well as risk indicators to enable a comprehensive evaluation and psychosocial accompaniment.

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**Table 1. Characterization of the judges according to age, profession, professional training and time of clinical experience. Ribeirão Preto (SP), Brazil (2017)**

| Judge | Age | Profession | Professional Training | Clinical Experience (years) |
|-------|-----|------------|-----------------------|----------------------------|
| 1     | 30  | Nurse      | Master                | 9                          |
| 2     | 30  | Nurse      | Master/Ph.D. student  | 9                          |
| 3     | 23  | Psychologist | Specialization      | 1                          |
| 4     | 36  | Nurse      | Ph.D. student         | 12                         |
| 5     | 37  | Doctor     | Ph.D.                 | 12                         |

**Table 2. Distribution of evaluations according to their relevance by section of the instrument. Ribeirão Preto (SP), Brazil (2017)**

| Section | Appearance (%) | Clarity/Understanding (%) | Content (%) | Efficiency/Consistency (%) | Objectivity (%) | Validity (%) |
|---------|----------------|---------------------------|-------------|----------------------------|-----------------|--------------|
| A       | 100.0          | 100.0                     | 100.0       | 100.0                      | 100.0           | 100.0        |
| B       | 100.0          | 100.0                     | 97.5        | 100.0                      | 100.0           | 97.5         |
| C       | 95.0           | 85.0                      | 90.0        | 90.0                       | 90.0            | 90.0         |
| D       | 100.0          | 100.0                     | 98.0        | 96.0                       | 100.0           | 96.0         |

**Table 3. Content Validation Index of the sections of the instrument. Ribeirão Preto (SP), Brasil (2017)**

| Sections | A | B | C | D | E | F |
|----------|---|---|---|---|---|---|
| VCI      | 1 | 1 | 1 | 1 | 1 | 1 |
This information, along with socio-demographic aspects, life habits, coping and adaptation to illness, may support interventions of the interdisciplinary team during treatment, improving professional support for patients and their families.19

Content validation was carried out by five judges. According to the analyses, the lowest percentage of agreement occurred in the item validity (95.9%), whose recommendations were accepted by the judges, according to the objective of the instrument.

The results of the evaluations carried out by the judges indicated that the instrument is reliable, but that agreement is not a fixed property of the instruments of measures and there is no interference in the context of application. It is necessary that the judges are aware of the items contemplated by the instrument, as well as the criteria for their evaluation.10

It is extremely important to obtain judges, professionals with assistance and research experience, as well as the appropriate method to select these professionals to evaluate the instrument, and in this study the Fehring method was adopted with possible adaptations.11

The instrument obtained the maximum value of the VCI, indicating that the instrument was validated, since the sections of the instrument presented score of 1, being the ideal values ≥ 0.78.16

This instrument was validated to obtain data from a doctoral thesis, since a validated instrument for sociodemographic, clinical and therapeutic characterization of patients with chronic colorectal diseases was not found in national and international studies.

**CONCLUSION**

The instrument presents representativeness and comprehensiveness regarding the socio-demographic, clinical and therapeutic characteristics of patients with chronic colorectal diseases.

In view of the results of content validation, the application of this instrument to the characterization of patients with chronic colorectal diseases in research is recommended, as well as the identification of demands for interdisciplinary care with a holistic perspective.

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