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EVALUATION AND CLASSIFICATION OF VAGINAL STENOSIS IN BRACHYTHERAPY: INSTRUMENT CONTENT VALIDATION FOR NURSES

Rafaela Dutra Nunes da Silva², Luciana Martins da Rosa³, Vera Radünz⁴, Daiana Cesconetto⁵

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² Nurse. UFSC. Florianópolis, Santa Catarina, Brazil. E-mail: rafaeladnunes@hotmail.com

³ Ph.D. in Nursing. Professor, Nursing Department and Postgraduate Program in Nursing, UFSC. Florianópolis, Santa Catarina, Brazil. E-mail: luciana.m.rosa@ufsc.br

⁴ Ph.D. in Nursing. Professor, Nursing Department, UFSC. Florianópolis, Santa Catarina, Brazil. E-mail: vera.radunz@ufsc.br

⁵ M.Sc. in Nursing. Nurse, *Hospital Governador Celso Ramos*. Florianópolis, Santa Catarina, Brazil. E-mail: daiana.prince@hotmail.com

ABSTRACT

Objective: to validate the content of an instrument prepared for evaluation and classification of vaginal stenosis after brachytherapy for its application by nurses.

Method: a methodological study that included ten nurses who are experts in brachytherapy. The data collection was performed between December 2015 and April 2016 and it was carried out through the application form made available to experts via the Google Drive/Microsoft® tool in three validation rounds, conducted by the Delphi Technique; 12 contents were evaluated. The data analysis was performed by calculating the Content Validity Index - CVI.

Results: in the first round, the use of intimate tampons was excluded (CVI=0.4), other contents have been adjusted, as well as the appearance of the instrument, according to the experts' recommendations. The content in the third round of evaluation reached the CVI=1.

Conclusion: the instrument content validation standardizes the technique; consequently, it increases and qualifies the clinical practice and research development.

DESCRIPTORS: Nursing. Oncology. Brachytherapy. Validation study. Pathological constriction. Cervical cancer.

AVALIAÇÃO E CLASSIFICAÇÃO DA ESTENOSE VAGINAL NA BRAQUITERAPIA: VALIDAÇÃO DE CONTEÚDO DE INSTRUMENTO PARA ENFERMEIROS

RESUMO

Objetivo: validar os conteúdos de um instrumento elaborado para avaliação e classificação da estenose vaginal pós-braquiterapia para aplicação por enfermeiros.

Método: estudo metodológico que incluiu dez enfermeiros *experts* em braquiterapia. A coleta de dados foi realizada entre dezembro de 2015 a abril de 2016 e ocorreu com a aplicação de formulário disponibilizado aos *experts* via ferramenta do Google Drive/Microsoft® em três rodadas de validação, conduzida pela Técnica Delphi; 12 conteúdos foram avaliados. A análise dos dados ocorreu pelo cálculo do Índice de Validade de Conteúdo - IVC.

Resultados: na primeira rodada, o uso de absorventes íntimos (tampões) foi excluído (IVC=0,4), outros conteúdos foram ajustados, bem como a aparência do instrumento, de acordo com as recomendações dos *experts*. Os conteúdos na terceira rodada de avaliação atingiram o IVC=1.

Conclusão: a validação de conteúdo de instrumento padroniza a técnica, conseqüentemente, incrementa e qualifica a prática clínica e o desenvolvimento de pesquisas.

DESCRIPTORIOS: Enfermagem. Oncologia. Braquiterapia. Estudo de validação. Constricção patológica. Câncer do colo do útero.

INDICADORES ANTROPOMÉTRICOS COMO PREVISORES DEL SÍNDROME METABÓLICO EN LOS ADOLESCENTES

RESUMEN

Objetivo: prever el síndrome metabólico en adolescentes a partir de indicadores antropométricos por análisis de sensibilidad y especificidad de los puntos de corte.

Método: estudio transversal y descriptivo en una muestra estratificada de 716 adolescentes de 10 a 19 años seleccionados por muestreo aleatorio simple en 30 escuelas públicas, municipales y estatales localizadas en Picos, Piauí, en la Región Noreste del Brasil. La obtención de datos se realizó en el período de Agosto hasta Diciembre del 2014 y en Marzo del 2015. Se investigaron los factores índice de masa corporal y el índice de conicidad. El síndrome metabólico se identificó a partir de los criterios adaptados para la edad.

Resultados: se observó la prevalencia de estudiantes del sexo femenino (61,3%) y la prevalencia del síndrome metabólico fue del 3,2%. El área sobre la curva de Características de Operación del Receptor mostró que el índice de masa corporal y el índice de conicidad se mostraron eficientes para la previsión del síndrome metabólico tanto en la muestra total como en la estratificación por sexo.

Conclusión: los indicadores antropométricos índice de masa corporal e índice de conicidad fueron buenos previsores del síndrome metabólico en esa población.

DESCRIPTORES: Adolescente. Síndrome X metabólico. Indicadores antropométricos. Factores de riesgo. Obesidad.

INTRODUCTION

The cervical cancer is one of the cancers that most affects women in Brazil and all over the world. In the genital tract, the cancer of the body of the uterus and ovary has also a significant incidence in the female gender, requiring specific care regarding the women's health. The worldwide incidence of cervical cancer by the year 2020 will be of approximately 609 thousand new cases, of the cancer of the body of the uterus 386 thousand and the of ovary cancer 282 thousand.¹ In Brazil, in 2017, it is estimated that there will be 16,340 new cases of cervical cancer, 6,950 of the body of the uterus and 6,150 of ovary.²

The brachytherapy, an antineoplastic therapy that delivers ionizing radiation near the tumor, is one of the main therapeutics in the treatment of cancers of the genital tract³ and, in the short or long term, it may lead to vaginal stenosis.⁴ The vaginal stenosis can negatively affect women's behavior, health, and sexual response, as physical changes affect libido and the sexual pleasure. This impairment is also exacerbated by the other effects of the disease treatment, which are usually related to the chemotherapeutic therapy (associated with the brachytherapy), as well as to the uncertainties regarding the illness and the psycho-emotional and physical changes, which can compromise the quality of life, especially the sexual life after the end of the brachytherapy.⁵

Despite the impairments resulting from the vaginal stenosis after brachytherapy, studies indicate the absence of standardization for the evaluation and classification of vaginal stenosis.⁶⁻⁸ The lack of standardization hinders the clinical practice and the adequate evaluation of the woman's health condition. It is important to highlight that, after the end of the brachytherapy, the woman returns to the

public units specialized in radiotherapy about 30 days later for the follow-up assessment. After that, she maintains a health monitoring in the Primary Care Network.

However, it is pointed out the lack of professional qualification of nurses for the cancer care, being that the qualification deficit in primary care is clearer in the perception of the professionals themselves, since there is no permanent education planning for the scientific improvement inherent to the user's demands, linked to the epidemiological profile of the neoplasms in the current context.⁹ Usually, women after brachytherapy have the Basic Health Units as the main door to access healthcare.

In view of this context, a study was carried out to identify the most used method for the evaluation and classification of vaginal stenosis resulting from brachytherapy.¹⁰ The study was a narrative review conducted in July 2013, in the Medical Literature Analysis and Retrieval System Online (MEDLINE) Virtual Health Library (Biblioteca Virtual da Saúde), Scientific Electronic Library Online (SciELO) and PubMed of the US National Library of Medicine, with the following criteria: no time limit, text available for complete online access, English, Portuguese and Spanish languages, all indexes, and in the studies that are part of two scientific reviews that address vaginal stenosis.⁶⁻⁷ The descriptors used in the search were: brachytherapy and vaginal stenosis; radiotherapy and vaginal stenosis; uterine cervical neoplasms and vaginal stenosis.¹⁰

This study has found, as in the other studies already mentioned,⁶⁻⁸ the diversity of the evaluation and classification methods of vaginal stenosis and the lack of standardization of techniques.

In order to register the diversity of methods, the main findings of this investigation are presented

below. Studies¹¹⁻¹² that investigated vaginal stenosis associated with pelvic brachytherapy have considered such toxicity as vaginal narrowing and/or shortening, interfering with the use of internal tampons, sexual activity or physical examination, with vaginal dryness or dyspareunia. For the classification of vaginal stenosis, the following criteria have been used: degree 1 - asymptomatic, mild vaginal shortening or narrowing; degree 2 - vaginal narrowing and/or shortening not interfering with physical examination; degree 3 - vaginal narrowing and/or shortening interfering with the use of tampons, sexual activity, physical activity or physical examination; degree 4 - there is no determination; degree 5 - death.

A second study¹³ has used the following classification: degree 1 - absence of stenosis; degree 2 - partial stenosis; degree 3 - complete obliteration; degree 4 - presence of severe complications associated with tissue changes caused by radiotherapy such as ulcer and necrosis; degree 5 - vesical and intestinal fistulas.

A third study¹⁴ has used the classification: degree 1 - absence of stenosis; degree 2 - presence of stenosis in the first proximal third of the vagina; degree 3 - presence of stenosis beyond the first third of the vagina until complete obliteration.

A fourth study¹⁵ has used the classification: degree 1- severe vaginal stenosis; degree 2 - moderate stenosis, however, the criteria used for this evaluation were not described.

A fifth study¹⁶ has classified the stenosis as mild and the mucosal and vaginal size as normal, partially modified or severely modified, however, it did not present the criteria used for these classifications.

Authors who investigated the sexual dysfunction in women with advanced cervical cancer undergoing exclusive radiotherapy, vaginal stenosis was defined as the narrowing of the vaginal canal which makes it impossible during the gynecological examination to completely introduce the number 1 gynecological speculum,¹⁷ or the shortening of the vagina, less than 8 to 9 centimeters in length.¹⁸⁻¹⁹

Another study reported that vaginal stenosis in the clinical examination is characterized by the inability of two examiners to insert two fingers into the vaginal canal.²⁰ The stenosis was also evaluated by comparing the size of the vagina before and after the completion of brachytherapy.²¹ Or, it was also evaluated by comparing and measuring the difference between the distance from the upper edge of the pubis and the apex of the cylinder inserted in the

vagina, associated with a radiological examination, before brachytherapy and after the second application of the therapy.²²

The result of this investigation,¹⁰ associated with practical experience, has allowed the preparation of contents for the creation of an instrument that standardizes the evaluation and classification of vaginal stenosis after brachytherapy to be applied by nurses.

The contents defined for evaluation, classification, as well as nursing records (interventions and referrals) are presented in Table 1. The contents of this instrument were defined by the grouping of the information found in the studies included in the previously mentioned narrative review¹⁰ and by the clinical experience of the authors in the development of nursing consultations in the oncological context.

Therefore, the objective of this study is to: validate the contents of an instrument¹⁰ for the evaluation and classification of vaginal stenosis after brachytherapy for application by nurses.

The content validity consists of a process that associates abstract concepts and measurable indicators, allowing us to evaluate the extent to which each item of the measure proves the phenomenon of interest and the dimension of each item within what it proposes to investigate. This process consists of two steps: one of them builds the development of the instrument and the other is the analysis and judgment of the specialists, judges who have experience in a specific area, who will be responsible for analyzing whether the content is correct and appropriate to what it is proposed.²³

METHOD

This is a methodological study that used the Delphi Technique and the Content Validity Index (CVI) for instrument validation, approved by the Research Ethics Committee of the *Universidade Federal de Santa Catarina*, under the protocol No. 1.377.349, CAAE No. 49461715.7.0000.0121.

Methodological studies allow the development, validation and evaluation of tools and research methods.²⁴ The Delphi Technique consists of a method in which the judgment of information occurs in order to obtain the consensus of experts (judges evaluators) in the researched topic. For doing so, successive questionnaires are applied in order to reach a consensus among the specialists, with the objective of perfecting a certain instrument, and this happens after successive changes in the instrument.²⁵⁻²⁷

For the application of this technique, the researcher must elaborate an objective questionnaire, structured or not, exploring the aspects that demand the opinion of the experts, in order to obtain a consensus on the clarity of the contents. The questionnaire should circulate among the group of experts so that they reach a consensus, most often for three cycles (validation rounds), what may be increased depending on the need of the study. The most common scaling methods are the Likert, Thurstone and Guttman ones; in this study we have used the Likert scaling.²⁵

The Likert scale usually presents a staggering of three or more points, whose evaluating judge registers his/her agreement, disagreement or doubt, as to what is stated in each item evaluated, regarding the measurement capacity to which the instrument proposes.²⁷

The first round of validation is the moment to identify the study objectives, and the instructions for completing and returning the questionnaire are provided. In the second cycle, the answers obtained in the first round should be made available to the specialists to follow the results being built. New questions or modified questions are submitted for re-validation. The third round is the moment when the researcher looks for consensus, and can maintain or eliminate research questions. The level of consensus is reserved to the researcher, and in the literature it ranges from 50% to 80%.²⁵ In this study, the consensus level was set at 78%.²⁸

Ten brachytherapy expert nurses participated in this study. The number of participants was defined by non-probabilistic sample. The total number of participants recommended for inclusion in validation studies is controversial; however, a recommendation from five to ten experts is common.²⁸ In this study, we chose to include ten. In the Delphi Technique, it is common for experts to drop out in successive rounds of validation, thus, it was defined that dropouts above 30% would require inclusion of new ones, however, it did not happen in this study.

The following criteria for selecting the experts were established: to act in a brachytherapy clinic; to have at least six months of experience in the field; to have at least a postgraduate degree; and, to be referred by the nursing coordinator of a cancer institution. Thus, we have initially contacted nursing coordinators of oncological institutions located in the Southern Region of Brazil (considering that this study was based on the need of an institution in the State of Santa Catarina) and in the State of Rio de Janeiro.

In the selection, twelve nurses were invited to participate in this study, ten accepted, four of them worked in Santa Catarina, three in Rio Grande do Sul, two in Paraná and one in Rio de Janeiro. If the minimum number of nurses was not reached, the search for other experts would be extended to institutions located in other states of Brazil, however, the expansion of the selection was not necessary.

For the data collection, a form was created in the Google Drive® storage service, containing the contents (items for the evaluation and classification of vaginal stenosis and an item for recording the interventions and nursing referrals) that make up the instrument to be validated by this study (Table 1). For each content presented in the form, the Likert scale was inserted with the following alternatives: totally agree; partially agree, disagree and space for suggestions and comments of the evaluating judges.

In addition to the contents of the instrument, some other data were included in the form to characterize the professional profile of the evaluating judges, which were: age, schooling, training time and experience in the care of women undergoing brachytherapy.

The form was sent to the evaluating judges via Internet and an electronic address was created exclusively for this purpose. Before sending the form, contact was made by e-mail, clarifying the reasons for the study, how it would be developed and the participation of the evaluating judges. At this moment, the signing of the Free and Informed Consent Term was requested. Upon acceptance by the study participant, the form was submitted and the validation rounds were initiated.

For each item evaluated, the Content Validity Index (CVI) was calculated, ranging from 0 to 1. The $CVI > 0.78$ was considered the minimum value for content validation. For CVI below this value was considered contents that needed to be revised or eliminated (contents that received partial agreement or disagreement in the evaluation of the evaluating judges). The minimum CVI agreement followed the recommendations when more than five evaluating judges were included. For the calculation of the CVI, the number of total agreements was divided by the number of total answers obtained by the evaluation of the evaluating judges.²⁸

The recommendations of the evaluating judges were included in the contents of the instrument for a new validation round, in search of $CVI=1$. In this study, three validation rounds were carried out between December 2015 and April 2016.

Also, it is recorded that the authors of the study¹⁰ who prepared the instrument to be validated by this investigation authorized its accomplishment.

RESULTS

The first round of validation had ten evaluating judges. The second and third round had nine evaluating judges. The withdrawal of an evaluating judge occurred due to the removal of one of the nurses from their professional relationship.

Regarding the profile of the evaluating judges, it was identified that the time of training as a nurse ranged from one to 32 years, most of them had more than ten years of training; seven with a specialist title and three with a master's degree. The experience time in the brachytherapy area ranged from ten months to nine years, most of them having three years or more.

The total number of agreement and CVI per round of validation obtained in the validation rounds is presented in Table 1.

Table 1 - Number of total agreement and Content Validity Index per validation round. Florianópolis-SC, Brazil, 2016

Content	1st Round		2nd Round		3rd Round	
	n Total agreement	CVI*	n Total agreement	CVI*	n Total agreement	CVI*
1 Discomforts and questions	8	0.80	8	0.89	9	1
2 Sexual relations	7	0.70	7	0.78	9	1
3 Vaginal dilation exercises	8	0.80	8	0.89	9	1
4 Pain perception	4	0.40	7	0.78	9	1
5 Vaginal bleeding	7	0.70	7	0.78	9	1
6 Use of intimate tampons	4	0.40	Content excluded in the 1st round			
7 Previous gynecological examination	7	0.70	7	0.78	9	1
8 Vaginal lubrication	7	0.70	7	0.78	9	1
9 Gynecological examination	7	0.70	7	0.78	9	1
10 Classification of vaginal stenosis after the interview and gynecological examination	5	0.50	7	0.78	9	1
11 Nursing prescriptions oriented or implemented	7	0.70	7	0.78	9	1
12 Referrals to other indicated professionals	8	0.80	8.00	0.89	9	1

* CVI=Content Validity Index (ten evaluating judges in the 1st round of validation and nine in the 2nd and 3rd rounds of validation).

In the first round of validation, three contents reached the CVI above 0.78; six reached a value of 0.70 and three contents reached CVI<0.7, they were: pain perception (CVI=0.4 for total agreement, CVI=0.5 for partial agreement, CVI=0.1 for disagreement); use of intimate tampons (CVI=0.4 for total agreement, CVI=0.5 partial agreement, CVI=0.1 for disagreement); and classification of vaginal stenosis (CVI=0.5 for total agreement; CVI=0.5 for partial agreement).

The content regarding the use of intimate tampons was excluded from the instrument after the

first round of validation. The exclusion, as recommended by the evaluating judges, occurred due to the fact that women after gynecological brachytherapy did not menstruate anymore, consequently there was no need for the use of the intimate tampons. This exclusion led to the alteration of the contents related to the classification of vaginal stenosis in degrees 1 and 2, since they contained a description of the use of an intimate tampon.

In the second round, all contents, after changes made as suggested by the evaluating judges, reached the minimum CVI for validation

(0.78). But, considering new recommendations from the evaluating judges in the second round, the contents were adjusted again and the third round of validation was carried out in search of the greatest possible consensus. In the third round of validation, the CVI=1 was reached in all contents. The evaluating judges' comments were acknowledgments regarding the invitation received for this validation and praise regarding the study initiative.

Chart 1 presents all the contents that are part of the instrument, before and after validation. The content differences (build from the changes suggested by the evaluating judges), defined in the validation process, and are presented in words written in italics in the right column.

Of the 12 contents evaluated by the judges in the first round, 11 were validated after the inclusion of the suggested recommendations and one was excluded.

Chart 1 - Contents of the Instrument for Evaluation and Classification of Vaginal Stenosis before and after validation. Florianópolis-SC, Brazil, 2016

Before validation	After validation
<p>Discomforts and Questions</p> <ul style="list-style-type: none"> - Is there any discomfort or complaint you may want to report that have come up after the end of brachytherapy? - Are there any questions you want to ask? 	Initial content maintained.
<p>Sexual relations</p> <ul style="list-style-type: none"> - Do you have sexual relations? () Yes () No - If so, how many times a week? - If not, why not? 	<p>Sexual relations</p> <ul style="list-style-type: none"> - Do you have sexual relations with vaginal penetration? () Yes () No - <i>How many times a week?</i> - <i>If not, Why don't you have sexual relations with vaginal penetration?</i>
<p>Vaginal dilation exercise</p> <ul style="list-style-type: none"> - Do you do vaginal dilation exercise? () Yes () No - If so, how many times a week? - If not, why not? - Please, describe the directions given by the nurse for the performance of vaginal physiotherapy: () reported in full () reported partially () did not report - If REPORTED PARTIALLY, record the identified health education needs: 	<p>Vaginal dilation exercise</p> <ul style="list-style-type: none"> - Do you do vaginal dilation exercise? () Yes () No - <i>How many times a week? If not, why don't you perform the exercises?</i> - Please, describe the directions given by the nurse and/or other professional of the health team to perform the vaginal dilation exercise: () reported in full <i>the institutionally recommended care</i> () reported partially () did not report - If REPORT PARTIALLY or DID NOT REPORT, record the health education needs:
<p>Pain perception</p> <ul style="list-style-type: none"> - Do you feel pain during the sexual act or at another moment? () Yes () No - If so, what is the pain intensity (from 1 to 10)? - If so, what is the location of the pain? - If so, how long does the pain last? - If so, what are the characteristics of pain? - If so, what do you do to control the pain? 	<p>Pain perception</p> <ul style="list-style-type: none"> - <i>During the sexual act, or at another moment, do you feel pain in the region where the radiotherapy was performed (pelvic, vaginal, perianal region)?</i> () Yes () No - <i>What is the intensity (from 1 to 10), duration, characteristics and location of the pain?</i> - <i>What are the strategies used for controlling the pain?</i>

<p>Vaginal bleeding</p> <ul style="list-style-type: none"> - Do you have any bleeding or other vaginal secretion? () Yes () No - If so, what are the characteristics of the bleeding or secretion? - If so, when (approximate start date) did this bleeding or secretion start? - Are you under treatment to control the bleeding and/or vaginal secretion? () Yes () No - If so, what is the treatment? - If not, why don't you or why didn't you seek care to start the treatment? 	<p>Bleeding and vaginal secretion</p> <ul style="list-style-type: none"> - Do you have any vaginal bleeding? () Yes () No, or do you have any other type of secretion? () Yes () No - What is the start date and the characteristics of the bleeding and/or secretion? - Are you under treatment to control the bleeding and/or vaginal secretion? () Yes () No. What is the treatment performed? - If the patient does not perform treatment, ask and record the reason for this attitude.
<p>Use of intimate tampons</p> <ul style="list-style-type: none"> - Do you use intimate tampons? () Yes () No - If not, why not? 	Content excluded.
<p>Previous gynecological examination</p> <ul style="list-style-type: none"> - Have you had a gynecological examination after the end of the brachytherapy? () Yes () No - If so, when were you examined? ___/___/___ - Was there any difficulty in performing the previous gynecological examination? () Yes () No - If so, what were the difficulties encountered? - If not, why weren't you examined? 	<p>Previous gynecological examination</p> <ul style="list-style-type: none"> - Have you had a gynecological examination after the end of the brachytherapy? () Yes () No - When were you examined after the end of the brachytherapy? - Was there any difficulty in performing the previous gynecological examination? () Yes () No - What were the difficulties and/or discomforts felt? - If you did NOT undergo gynecological examination after the end of the brachytherapy, why not?
<p>Vaginal lubrication</p> <ul style="list-style-type: none"> - Do you use or feel the need to use vaginal lubricant? () Yes () No - If so, why do you feel the need? - If so, which lubricant do you use? - If so, how often do you use the lubricant? 	<p>Vaginal dryness and use of lubricant</p> <ul style="list-style-type: none"> - Do you experience vaginal dryness? () Yes () No - Do you use or feel the need to use vaginal lubricant? () Yes () No - Why do you feel the need to use lubricant? - What is the lubricant and how often do you use it?
<p>Gynecological examination:</p> <ul style="list-style-type: none"> - Examination performed () Yes () No. - Size of the speculum used: () small () medium () large - Characteristics of the vaginal canal and uterus that show physiological abnormalities: - If there were any obstacles to the gynecological exam, mention the reason(s): - Was the collection of material for oncotic colpocytology performed? () Yes () No - If the oncotic colpocytology was not performed, mention the reason(s): 	Initial content maintained.

<p>Classification of vaginal stenosis*: () Degree 0; () Degree 1; () Degree 2; () Degree 3; () Degree 4; () Degree 5. To define the degree of vaginal stenosis consider the following characteristics: Degree 0: asymptomatic woman; Degree 1: woman who reports some vaginal discomfort, but what does not prevent the use of tampons, sexual activity and gynecological examination; Degree 2: woman who presents vaginal narrowing and/or shortening that partially interferes with the use of intimate tampons, sexual activity and gynecological examination; Degree 3: woman who presents complete constriction of the vagina, identified in the visual inspection during the gynecological examination and that makes it impossible to perform the gynecological examination and sexual activity; Degree 4: woman who presents ulcer and necrosis in the vaginal canal (presence of ulcer and necrosis confirmed by medical evaluation and/or examinations); Degree 5: woman who presents vesical and/or intestinal fistulas (presence of ulcer and necrosis confirmed by medical evaluation and/or examinations).</p>	<p>Classification of vaginal stenosis*: () Degree 0; () Degree 1; () Degree 2; () Degree 3; () Degree 4; () Degree 5. To define the degree of vaginal stenosis consider the following characteristics: Degree 0: asymptomatic woman; <i>Degree 1: woman who reports some vaginal discomfort, but what does not prevent sexual activity, the performance of gynecological examination or the recommended vaginal dilation exercise after brachytherapy;</i> <i>Degree 2: woman who presents vaginal narrowing and/or shortening that partially interferes with the use of intimate tampons, sexual activity, gynecological examination, and in the exercise of recommended vaginal dilation after brachytherapy;</i> Degree 3: woman who presents complete constriction of the vagina, identified in the visual inspection during the gynecological examination and that makes it impossible to perform the gynecological examination and sexual activity; Degree 4: woman who presents ulcer and necrosis in the vaginal canal (presence of ulcer and necrosis confirmed by medical evaluation and/or examinations); Degree 5: woman who presents vesical and/or intestinal fistulas (presence of ulcer and necrosis confirmed by medical evaluation and/or examinations).</p>
<p>Nursing prescriptions oriented or implemented</p>	<p><i>Record of nursing interventions oriented or implemented</i></p>
<p>Referrals to other indicated professionals</p>	<p>Initial content maintained.</p>

* The items that are part of the classification of vaginal stenosis were built based on some scientific publications,¹⁷⁻¹⁹ on the clinical experience in Oncology and on the changes proposed by the evaluating judges.

Source: Data from the research and study entitled *Evaluation and classification of vaginal stenosis after brachytherapy*.¹⁰

DISCUSSION

The perception of discomfort and pain is relative to each person and depends on factors such as threshold of individual pain, past experiences and life history. Besides that, the pain for women undergoing brachytherapy may change under the influence of emotional, social, and spiritual factors.²⁹ Thus, the clearer the process of evaluation of pain complaints after gynecological brachytherapy, the more effective the interventions for the nursing care, thus, the judges' contributions qualified the collection of nursing data.

The use of intimate tampons in content validation was excluded. This validation was considered relevant because the absence or decrease of the ovarian function, induced by radiotherapy, leads to an estrogen deficiency and absence of menstruation,⁵

consequently, there is no reason for the use of an intimate tampon. Such observation was not taken into account when the content of the instrument was elaborated, as recommended by the *Common Terminology Criteria for Adverse Events*³⁰ and its use in a study investigating the vaginal toxicity associated with brachytherapy,¹¹ which guided the preparation of the instrument validated here. However, the classification proposed by the *Common Terminology Criteria for Adverse Events*³⁰ is not limited to the vaginal stenosis consequent to the gynecological brachytherapy, which once again justifies the validation of the evaluating judges.

As for the vaginal bleeding, this side effect is among the discomforts and/or symptoms most frequently reported by women during and after the gynecological brachytherapy.^{29,31} The bleeding usually results from the dryness and narrowing of the

vaginal canal, resulting from the ionizing radiation, which can occur continuously, intermittently or only during the vaginal penetration of the sexual act.⁵

The inclusion of the item vaginal secretion, requested by the evaluating judges, was considered pertinent, since bleeding is one of the possible variations, and it may be present in the serous, serous-bleeding, hemorrhagic and/or purulent form, resulting from the tissue damage. Considering the variations obtained, it is understood that the suggestion of the evaluating judges to include the secretion item, separately from the item bleeding, qualifies the instrument, improving the investigation and the form of registration of the nursing data collection.

Vaginal secretions may vary in quantity, causes and characteristics (color, odor, pruritus, burning and thickness), and it may or may not be related to vaginal stenosis. Regardless of the origin of the secretions, if present, they need to be identified and treated. They may be a consequence of the presence of fistulas. Rectovaginal fistulas are the result of actinic retina, which can occur in any patient undergoing pelvic radiotherapy.³² A study indicates that actinic retina occurs in 59% of the cases, actinic cystitis in 29% and fistulas in 10%.⁵

For the characterization of the vaginal canal, it is suggested that its characteristics, before the beginning of the pelvic brachytherapy, are part of the nursing notes. Only then it will be possible to compare the characteristics before and after the brachytherapy, making it easier to evaluate and classify the vaginal stenosis resulting from the therapy and the interventions that should be implemented to care for women.

Some characteristics are common to the vaginal canal due to vaginal stenosis. A study points out that the toxicity from the ionizing radiation can manifest itself after three years of treatment completion. The changes observed include a change in the color of the mucosa, which becomes pale and may progress from mild to moderate or severe pallor. This pallor is related to thinning, dryness, atrophy, inflammation and/or fibrosis of the vaginal mucosa. Therefore, pallor may be an indicator of late vaginal stenosis.³³⁻³⁴

The shortening of the vagina is another characteristic that helps in the evaluation of the vaginal stenosis. For this reason, it is important to record the size of the vagina before the brachytherapy begins or the size of the speculum used in the gynecological examination. Its estimated length is 7 to 9 cm,³⁵ length less than 7 cm may indicate vaginal stenosis.

The terminology "prescription" involves an order (or orientation) or determination; and the

terminology "intervention" involves actions of orientation and actions to be performed by nurses and the nursing staff, that is, the second is more comprehensive. Thus, the recommendation of the experts to replace the term prescription for intervention is justified. The nursing interventions are established through the definition of nursing diagnoses and the identification of health problems or needs, and they aim to solve the problems and reach the nursing results. It should be highlighted that the Federal Nursing Council (*Conselho Federal de Enfermagem*) indicates the use of the term intervention or nursing actions.³⁶

Regarding the content presentation format, the evaluating judges suggested changes in the instrument's appearance. These changes are pertinent in validation studies because, even when considered as a subjective evaluation, they allow the improvement of the presentation, comprehension of the content, clarity and objectivity of the instrument, as well as they facilitate reading, interpretation of content and the objectivity of the instrument.^{27,37} Thus, all the evaluations and recommendations of the evaluating judges have made the instrument more suitable to be applied by nurses, allowing the increment of the clinical practice.

Finally, it is understood that the validation of the content of the instrument meets what was idealized in the article "Evaluation and Classification of Vaginal Stenosis After Brachytherapy",¹⁰ that is, it contributes to the nurses' evaluation and classification of the presence or absence of vaginal stenosis, which, consequently, allows the establishment of a nursing diagnoses and interventions for the care and prevention of this toxicity caused by the pelvic brachytherapy.³⁸ It is important to emphasize that the validation performed in this study was of content and does not configure a psychometric validation of the instrument, an aspect that is configured as a limitation of this article.

CONCLUSION

The contents of the instrument proposed in the article "Evaluation and classification of high dose rate of vaginal stenosis after brachytherapy" were validated by this study. The content regarding the use of intimate tampons was excluded. Therefore, the evaluation and classification of vaginal stenosis should cover the following contents, as validated by this study: discomfort and questioning of women, sexual relations, performing the vaginal dilation exercise, pain perception, vaginal bleeding and secretion, previous gynecological examination, vaginal

dryness and use of lubricant, gynecological exam, classification of vaginal stenosis, record of oriented or implemented nursing interventions and referrals to other indicated professionals.

The experience of the brachytherapy expert nurses was essential in order to advance the validation of the contents. It is understood that the results obtained with the validation of the instrument will allow nurses and other professionals to use it in the care of women submitted to brachytherapy, which will result in a better preventive and/or diagnostic control of vaginal stenosis, better care choices and better possibilities of quality of life and sexual health. The standardization of the evaluation and classification of vaginal stenosis after brachytherapy improves and qualifies the clinical practice, as well as it attracts possible research in this area.

REFERENCES

1. Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M ET al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. *International Journal of Cancer*. Published online 9 Oct 2014 [cited 2016 Aug 16]. Available from: <http://gco.iarc.fr/today/home>
2. Instituto Nacional do Câncer. Estimativa 2016: incidência do câncer no Brasil. Rio de Janeiro: INCA; 2015.
3. Silva RMV, Pinezi JCD, Macedo LEA, Souza DN. Current situation of high-dose-rate brachytherapy for cervical cancer in Brazil. *Radiol Bras*. 2014 May-Jun; 47(3):159-64. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4337132/>
4. Santos ALA, Moura JFP, Santos CAAL, Figueiroa JN, Souza AI. Avaliação da qualidade de vida relacionada à saúde em pacientes com câncer do colo do útero em tratamento radioterápico. *Rev Bras Cancerol* [Internet]. 2012 [cited 2016 Aug 16];3(58):507-15. Available from: http://www.inca.gov.br/Rbc/n_58/v03/pdf/21_artigo_avaliacao_qualidade_vida_relacionada_saude_pacientes_cancer_colo_uterotratamento_radioterapico.pdf
5. Vidal MLB, Santana CJM, Paula CL, Carvalho MCMP. Disfunção sexual relacionada à radioterapia na pelve feminina: diagnóstico de enfermagem. *Rev Bras Cancerol* [Internet]. 2012 [cited 2016 Aug 16]; 1(59):17-24. Available from: http://www.inca.gov.br/rbc/n_59/v01/pdf/04-disfuncao-sexual-relacionada-a-radioterapia-na-pelve-feminina-diagnostico-de-enfermagem.pdf
6. Silva MPP, Gannuny CS, Aiello NA, Higino MAR, Ferreira NO, Oliveira MMF. Métodos avaliativos para estenose vaginal pós-radioterapia. *Rev Bras Cancerol* [Internet]. 2009 [cited 2016 Aug 16]; 1(56):65-70. Available from: http://www.inca.gov.br/rbc/n_56/v01/pdf/10_revisao_de_literatura_metodos_avaliativos_estenose_vaginal.pdf
7. Lancaster L. Preventing vaginal stenosis after brachytherapy for gynaecological cancer: an overview of Australian practices. *Eur J Oncol Nurs* [Internet]. 2004 [cited 2016 Aug 16]; 8(1):30-9. Available from: <http://www.sciencedirect.com/science/article/pii/S1462388903000590>
8. International Clinical Guideline Group. International guidelines on vaginal dilation after pelvic radiotherapy. Department of Gynaecology, Royal United Hospital, Bath, UK: Owen Mumford; 2012 [cited 2016 Aug 16]. Available from: <http://www.ncsi.org.uk/wp-content/uploads/Inter-Best-Practice-Guide-Vaginal-Dilators-July-2012.pdf>
9. Cruz FS, Rossato LG. Cuidados com o paciente oncológico em tratamento quimioterápico: o conhecimento dos enfermeiros da Estratégia Saúde da Família. *Rev Bras Cancerol* [Internet]. 2015 [cited 2016 Sep 12]; 61(4):335-41. Available from: http://www1.inca.gov.br/rbc/n_61/v04/pdf/04-artigo-cuidados-com-o-paciente-oncologico-em-tratamento-quimioterapico-o-conhecimento-dos-enfermeiros-da-estrategia-saude-da-familia.pdf
10. Rosa LM, Hammerschmidt KSM, Radünz V, Ilha P, Tomasi AVR, Valcarenghi RV. Evaluation and classification of vaginal stenosis after brachytherapy. *Texto Contexto Enferm* [Internet]. 2016 [cited 2016 Aug 16]; 25(2):e3010014. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0104-07072016000200501&lng=en
11. Bahng AY, Dagan A, Bruner DW, Lin LL. Determination of prognostic factors for vaginal mucosal toxicity associated with intravaginal high-dose rate brachytherapy in patients with endometrial cancer. *Int J Radiat Oncol Biol Phys* [internet]. 2012 [cited 2014 Out 27]; 82(2):667-73. Available from: <http://www.sciencedirect.com/science/article/pii/S03603016110036515>
12. Gondi V, Bentzen SM, Sklenar KL, Dunn EF, Petereit DG, Tannehill SP, Straub M, Bradley KA. Severe late toxicities following concomitant chemoradiotherapy compared to radiotherapy alone in cervical cancer: an inter-era analysis. *Int J Radiat Oncol Biol Phys* [internet]. 2012 [cited 2014 Out 2014]; 84(4):973-82. Available from: <http://www.sciencedirect.com/science/article/pii/S036030161200137X>
13. Brand AH, Bull CA, Cakir B. Vaginal stenosis in patients treated with radiotherapy for carcinoma of the cervix. *Int J Gynecol Cancer*. 2006; 16(1):288-3.
14. Hartman P, Diddle AW. Vaginal stenosis following irradiation therapy for carcinoma of the cervix uteri. *Cancer*. 1972; 30(2):426-9.
15. Khor TH, Tuan JKL, Hee SW, Tham IWK. Radical radiotherapy with high-dose-rate brachytherapy for uterine cervix cancer long-term results. *Australas Radiol* [Internet]. 2007 [cited 2014 Out 27]; 51(6):570-

7. Available from: <http://onlinelibrary.wiley.com/doi/10.1111/j.1440-1673.2007.01895.x/pdf>
16. Schover LR, Fife M, Gershenson DM. Sexual dysfunction and treatment for early stage cervical cancer. *Cancer*. 1989; 63(1):204-12.
17. Bernardo BC, Lorenzato FRB, Figueiroa JN, Kitoko PM. Disfunção sexual em pacientes com câncer do colo uterino avançado submetidas à radioterapia exclusiva. *Rev Bras Ginecol Obstet* [internet]. 2007 [cited 2014 Oct 27]; 29(2):85-90. Available from: <http://www.scielo.br/pdf/rbgo/v29n2/05.pdf>
18. Flay L, Matthews JHL. The effects of raditherapy and surgery on the sexual function of women treated for cervical câncer. *Int J Radiat Oncol Biol Phys*. 1995; 31(2):399-440.
19. Bruner DW, Lanciano R, Keegan M, Corn B, Martin E, Hanks GE. Vaginal stenosis and sexual function following intracavitary radiation for the treatment of cervical and endometrial cancer. *Int J Radiat Oncol Biol and Phys*. 1993; 27(4):825-30.
20. Nunns D, Williamson K, Swaney L, Davy M. The morbidity of surgery and adjuvant radiotherapy in the management of endometrial carcinoma. *Int J Gynecol Cancer*. 2000; 10(3):233-8.
21. Decruze SB, Guthrie D, Magnani R. Prevention of vaginal stenosis in patients following vaginal brachytherapy. *Clin Oncol*. 1999; 11(1):46-8.
22. Katz A, Njuguna E, Rakowsky E, Sulkes A, Sulkes J, Fenig E. Early development of vaginal shortening during radiation therapy for endometrial or cervical câncer. *Int J Gynecol Cancer*. 2001; 11(3):234-5.
23. Medeiros Rosana Kelly da Silva, Ferreira Júnior Marcos Antonio, Pinto Diana Paula de Souza Rêgo, Vitor Allyne Fortes, Santos Viviane Euzébia Pereira, Barichello Elizabeth. Modelo de validação de conteúdo de Pasquali nas pesquisas em Enfermagem. *Rev Enf Ref* [Internet]. 2015 Fev [cied 2017 Jul 13]; serIV(4):127-35. Available from: <http://dx.doi.org/10.12707/RIV14009>
24. Lima Dalmo Valério Machado de. Research design: a contribution to the author. *Online Braz. J. Nurs* [Internet]. 2011 [cited 2017 Jul 13]; 10(2):. Available from: <http://www.objnursing.uff.br/index.php/nursing/article/view/3648>
25. Castro AV, Rezende M.A Técnica Delphi e seu uso na pesquisa de enfermagem: revisão bibliográfica. *REME rev min enferm* [Internet]. 2009 [cited 2016 Aug 31];13(3):429-34. Available from: <http://www.reme.org.br/artigo/detalhes/209>
26. Sousa CS, Turrini RNT. Construct validation of educational technology for patients through the application of the Delphi technique. *Acta Paul Enferm* [Internet]. 2012 [cited 2016 Aug 16]; 25(6):990-6. Available from: http://www.scielo.br/pdf/ape/v25n6/en_v25n6a26.pdf
27. Pasquali, L. Instrumentação psicológica: fundamentos e práticas. Porto Alegre (RS): Artmed; 2010.
28. Alexandre NMC, Coluci MZO. Validade de conteúdo nos processos de construção e adaptação de instrumentos de medidas. *Ciênc saúde coletiva* [Internet]. 2011 [cited 2016 Aug 31]; 16(7):3061-7. Available from: <http://www.scielo.br/pdf/csc/v16n7/06.pdf>
29. Soares MLCA, Trezza MCSF, Oliveira SMB, Melo GC, Lima KRS, Leite JL . The healing cost comfort and discomfort experiences of women undergoing brachytherapy. *Esc Anna Nery* [Internet]. 2016 [cited 2016 Aug 16]; 20(2):317-23. Available from: http://www.scielo.br/pdf/ean/v20n2/en_1414-8145-ean-20-02-0317.pdf
30. National Cancer Institute. National Institutes of Health. U.S. Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0: 2009 May 28,03: 2010 June 14 [Internet]. U.S.A: National Cancer Institute; 2010 [cited 2016 Apr 07]. Available from: http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf
31. Dallabrida FA, Loro MM, Rosanelli CLSP, Souza MM, Gomes JS, Kolankiewicz ACB. Qualidade de vida de mulheres tratadas por câncer do colo de útero. *Rev RENE* [Internet]. 2014 [cited 2016 Aug 16]; 15(1):116-22. Available from: <http://www.revistarene.ufc.br/revista/index.php/revista/article/viewFile/1487/pdf>
32. Teixeira FV, Denadai R, Ferraz RA, Goulart RA, Saad-Hossne R. Instilação de formalina endoluminal como opção terapêutica da retiteactínica hemorrágica. *Rev Bras Colo-proctol* [Internet]. 2011 [cited 2016 Aug 04]; 31(1):32-8. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0101-98802011000100005&lng=en
33. Yoshida K, Yamazaki H, Nakamura S, Masui K, Kotsuma T, Akiyama H et al. Longitudinal analysis of late vaginal mucosal reactions after high-dose-rate brachytherapy in patients with gynecological cancer. *Anticancer Res* [Internet]. 2014 [cited 2016 Aug 16]; 34(8):4433-8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25075082>
34. Yoshida K, Yamazaki H, Nakamura S, Masui K, Kotsuma T, Akiyama H, et al. Role of vaginal pallorreaction in predicting late vaginal stenosis after high-dose-rate brachytherapy in treatment-naïve patients with cervical cancer. *J Gynecol Oncol* [Internet]. 2015 [cited 2016 Aug 16]; 26(3):179-84. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25925294>
35. Ferreira DM, Bezerra ROF, Ortega CD, Blasbalg R, Viana PCC, Menezes MR, Rocha MS. Magnetic resonance imaging of the vagina: an overview for radiologists with emphasis in clinical decision making. *Radiol Bras* [Internet]. 2015 [cited 2016 Aug 16]; 48(4):249-59. Available from: <http://www.scielo.br/pdf/rb/v48n4/0100-3984-rb-48-04-0249.pdf>
36. Conselho Federal de Enfermagem. Resolução n. 358 de 15 de outubro de 2009: dispõe sobre a Sistematização

- da Assistência de Enfermagem e a implementação do Processo de Enfermagem em ambientes, públicos ou privados, em que ocorre o cuidado profissional de Enfermagem, e dá outras providências; 2009 [cited 2017 Jul 13]. Available from: http://www.cofen.gov.br/resoluo-cofen-3582009_4384.html
37. Pompeo DA, Rossi LA, Paiva L. Content validation of the nursing diagnosis nausea. *Rev Esc Enferm USP* [Internet]. 2014 [cited 2016 Aug 31]; 48(1):49-57. Available from: <http://www.scielo.br/pdf/reeusp/v48n1/0080-6234-reeusp-48-01-48.pdf> http://www.scielo.br/pdf/reeusp/v48n1/pt_0080-6234-reeusp-48-01-48.pdf
38. Pessi MR, Feuerchutte KK, Rosa, LM, Hammerschmidt KSA, Radünz V, Alvarez AM. Prevention of vaginal stenosis after brachytherapy: nursing intervention. *J Nurs UFPE online* [Internet]. 2016 [cited 2017 Jun 12]; 10(9):3495-502. Available from: http://www.revista.ufpe.br/revistaenfermagem/index.php/revista/article/view/7717/pdf_11076