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Protocol validation for care of patients with pulmonary hypertension

Validação de protocolo para assistência ao paciente com hipertensão pulmonar

Validación de protocolo para la atención al paciente con hipertensión pulmonar

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Abstract
*Introduction***:** Pulmonary hypertension is a serious disease defined by increased pressure in the pulmonary vessels. It is a clinical syndrome due to increased pulmonary vascular resistance, which occurs due to vasoconstriction and/or degeneration of the vascular bed of the lungs, causing progressive loss of gas exchange capacity. The need for the development and validation of a care protocol for patients with pulmonary hypertension admitted to intensive care units is pointed out through evaluation by specialists of items that are believed to be relevant. *Objective***:** To develop and validate a care protocol for patients with pulmonary hypertension in intensive care units. *Method***:** This is a methodological study to validate the content of a care protocol for patients with pulmonary hypertension, through the application of the Delphi technique, based on Spinola's theoretical framework. *Results***:**Twenty professionals were invited to participate in the evaluation of the instrument, and 13 agreed to participate; however, 9 evaluators participated in the first Delphi Round. The final construct remained with 4 topics and 23 items, and no item was removed after evaluation by the experts. *Conclusion***:** The protocol for care ofpatients with pulmonary hypertension is a practical instrument and aims to ensure patient safety and the quality of care provided in conjunction with technological advances. It is believed that the protocol will help multidisciplinary teams to promote safe, accurate and efficient care for patients with pulmonary hypertension in intensive care units.
Keywords: Validation studies; Pulmonary hypertension; Clinical protocols; Critical care; Complications.

Resumo
*Introdução***:** A hipertensão pulmonar (HP) é uma doença grave definida pelo aumento da pressão dos vasos pulmonares. Trata-se de uma síndrome clínica, devido ao aumento da resistência vascular pulmonar, que ocorre por vasoconstrição e/ou degeneração do leito vascular dos pulmões causando perda progressiva da capacidade de trocas gasosas. Aponta-se a necessidade da elaboração e validação de um protocolo de cuidados ao paciente com hipertensão pulmonar internado em Unidades de Terapia Intensivas (UTIs) por meio da avaliação, por especialistas, de itens os quais se acredita serem pertinentes. *Objetivo***:** Elaborar e validar um protocolo assistencial de cuidados ao paciente com hipertensão pulmonar na unidade de terapia intensiva. *Método***:** Trata-se de estudo metodológico, de validação do conteúdo de um protocolo assistencial de cuidados ao paciente com hipertensão pulmonar, por meio da aplicação da técnica Delphi baseado no referencial teórico de Spínola. *Resultados***:** Foram convidados 20 profissionais para participarem da avaliação do instrumento, dos quais 13 aceitaram participar, no entanto, 09 avaliadores participaram

da primeira Rodada de Delphi. O constructo final permaneceu com 04 tópicos e 23 itens e não teve nenhum item retirado após avaliação dos experts. *Conclusão***:** O protocolo para assistência ao paciente com hipertensão pulmonar é um instrumento prático e visa garantir a segurança do paciente e a qualidade da assistência prestada articulada aos avanços tecnológicos. Acredita-se que o protocolo contribuirá para que a equipe multiprofissional promova uma assistência segura, precisa e eficiente ao paciente com hipertensão pulmonar nas unidades de terapia intensivas.
Palavras-chave: Estudos de validação; Hipertensão pulmonar; Protocolos clínicos; Cuidados críticos; Complicações.

Resumen

*Introducción***:** La hipertensión pulmonar (HP) es una enfermedad grave definida por el aumento de la presión en los vasos pulmonares. Es un síndrome clínico, por aumento de la resistencia vascular pulmonar, que se produce por vasoconstricción y/o degeneración del lecho vascular de los pulmones, provocando una pérdida progresiva de la capacidad de intercambio gaseoso. Se destaca la necesidad de elaboración y validación de un protocolo de atención a pacientes con hipertensión pulmonar internados en Unidades de Cuidados Intensivos (UCI), a través de la evaluación, por parte de especialistas, de ítems que se crean relevantes. *Objetivo***:** Desarrollar y validar un protocolo de atención a pacientes con hipertensión pulmonar en la unidad de cuidados intensivos. *Método***:** Se trata de un estudio metodológico para validar el contenido de un protocolo de atención a pacientes con hipertensión pulmonar, mediante la aplicación de la técnica Delphi basada en el marco teórico de Spinola. *Resultados***:** 20 profesionales fueron invitados a participar de la evaluación del instrumento, de los cuales 13 aceptaron participar, sin embargo, 09 evaluadores participaron en la primera Ronda Delphi. El constructo final quedó con 04 temas y 23 ítems y no se eliminó ningún ítem después de la evaluación de los expertos. *Conclusión***:** El protocolo de atención al paciente con hipertensión pulmonar es un instrumento práctico y tiene como objetivo garantizar la seguridad del paciente y la calidad de la atención brindada en conjunto con los avances tecnológicos. Se cree que el protocolo ayudará al equipo multidisciplinario a promover la atención segura, precisa y eficiente de los pacientes con hipertensión pulmonar en las unidades de cuidados intensivos.
Palabras clave: Estudios de validación; Hipertensión pulmonar; Protocolos clínicos; Cuidado crítico; complicaciones.

1. Introduction

Pulmonary hypertension (PH) is a serious lung disease defined by increased pressure in the pulmonary vessels (above 25 mmHg at rest). It is a clinical syndrome, due to increased pulmonary vascular resistance (Health Care Secretariat, 2014), which occurs due to vasoconstriction and/or degeneration of the vascular bed of the lungs, causing progressive loss of gas exchange capacity. There is also the proliferation of smooth muscle and endothelium of pulmonary vessels, hypertrophy, and chronic inflammation, factors that can lead to overload on the right side of the heart (Jardim, et al., 2015).

Pulmonary hypertension is divided into five types: pulmonary arterial hypertension, which compromises the precapillary compartment; pulmonary hypertension caused by diseases that affect the left side of the heart, in which the hypertension of the pulmonary vessels occurs as a result of high pressure in the left chambers of the heart; pulmonary hypertension caused by lung diseases and/or hypoxia, which includes chronic obstructive pulmonary disease (COPD);chronic thromboembolic pulmonary hypertension and pulmonary hypertension caused by multifactorial or unclear mechanisms, including hematological diseases, sarcoidosis, fibrosing mediastinitis, Langerhans cell histiocytosis and other diseases(Simmonneau et al., 2019).

As for the signs and symptoms of PH, the most common are chest pain, chronic fatigue, dyspnea, lethargy, dizziness, and syncope. On cardiopulmonary physical examination, hyperphonesis of the second heart sound in the pulmonary focus, systolic pulsation in the 2nd left intercostal space, 3rd sound of the right ventricle, murmurs, jugular stasis, hepatojugular reflux, hepatomegaly, cyanosis, peripheral edema, and ascites may be noted (Junior, 2014). In the diagnostic investigation, tests such as electrocardiograms and chest X-rays have little efficacy. The main test for an effective diagnosis is the transthoracic echocardiogram (ECOTT), which allows the examination of cardiac chambers and valves, in addition to estimating the value of pulmonary artery systolic pressure and right atrium pressure, and providing information on the severity of PH. Chest CT, MRI, polysomnography, pulmonary function tests, and laboratory tests are also used (Messina, et al., 2015).

Pulmonary hypertension affects 25 million people worldwide (Brazilian Association of Friends and Relatives of Patients with Pulmonary Arterial Hypertension, n.d.), and between 1% and 5% of cases of the hepatosplenic form of schistosomiasis are related to PH. Scottish and French data indicate that there are between 15 and 70 cases per million inhabitants in these countries (Junior, 2014). In Brazil, there are about 60,000 cases (Brito, 2017). A study in a reference outpatient clinic in Bahia identified the prevalence of idiopathic pulmonary arterial hypertension, followed by PH caused by schistosomiasis (Machado, et al., 2009); another carried out in two reference centers in São Paulo presented the same results, in addition to being associated with connective tissue diseases in 10% of the cases (Lapa et al., 2006). Studies reveal that PH occurs from the third decade of life in women, while in men the disease usually occurs from the age of forty (Health Care Secretariat, 2014).

Treatment for PH is carried out according to the etiology of the disease and includes physical activity, smoking cessation, dietary sodium restriction, pregnancy guidance for women of childbearing age. To control right ventricular dysfunction, diuretics, vasodilators and inotropes are used. To prevent deep vein thrombosis and pulmonary thromboembolism, oral anticoagulants are used. Oxygen therapy is used in patients with PH from COPD and hypoxia. In a smaller number of cases, those preceded by congenital heart diseases, palliative surgical treatment is indicated. Lung or cardiopulmonary transplantation is indicated as the only alternative for patients with refractory right ventricular failure and critically ill patients (Health Care Secretariat, 2014; Coordinator, Ilha, Antônio and Lopes n.d.).

Care for patients with PH is certainly important, as is guidance, since PH has high rates of morbidity and mortality, especially when related to COPD. (Galiè et al., 2009). Health professionals are part of this context of providing direct care and are of great importance in intensive care, in which the patient's condition is more critical and team cooperation is essential to provide quality care.

The more studies there are on care for different diseases, the more standardized and effective the work becomes, developing care, revealing improvements for professionals and patients, and facilitating further studies. Astudy that aimed to evaluate the use of standard operating procedures (SOPs) showed that standardization of nursing care supports nurses' decision-making and reduces non-conformities, bringing benefits to both patients and nursing teams, and favoring teaching and learning in the area (Sales, et al., 2018). Another study showed the effectiveness of using a protocol in invasive hemodynamic monitoring at the bedside, emphasizing the achievement of better results for patients and, again, ease of decision-making (Ramos et al., 2008).

Current studies have widely used the Delphi technique, which uses an instrument to validate information through the judgment of experts, who do not need to meet and remain anonymous. It can be used in several areas of knowledge, and a literature review showed that it has a satisfactory outcome for health professionals (Castro & Rezende, 2009).

The Delphi technique was the method selected for the development and validation of the protocol in question. It enables a consensus among a group of experts in a certain area of knowledge about a phenomenon (Polit & Hungler, 2011; Spinola, 1984). A study on the care of septic patients in the ICUused it to construct a care protocol with 15 items. The study confirmed that the method favored achieving effective and quality care for these patients through standardization of care (Pedrosa, et al., 2018).

Another study carried out the validation of an instrument to assess the training of professionals in cardiopulmonary resuscitation. This research is of great importance for the care of patients with cardiorespiratory arrest, given that the impacts of care for these patients can be great. Above all, the Delphi technique was convenient in generating a good instrument to evaluate the teaching-learning process of professionals (Lucas, et al., 2018).

The same process was used in a doctoral thesis to develop a protocol for care of people with venous ulcers in primary care. The article found that the Delphi technique was advantageous for being flexible and valuing the opinion and knowledge

of the participating experts, allowing reflection on the behavior of professionals and the standardization of protocol to meet the needs of persons with venous ulcers (Costa, 2013).

It is understood that the validation of protocols and instruments with the Delphi technique is positive and can be used in order to consensually bring together actions that must be standardized in care, improving the quality of care for both professional practice and patients (Costa, 2013). The need for the development and validation of a care protocol for patients with PH is pointed out through the evaluation by specialists of items that are believed to be relevant. The protocol content validation is intended to be a fundamental phase in the instrument development process,in order to obtain reliable and safe applicability, supporting its use in hospital ICUs and in the teaching and training of new specialists. Such validation is essential for health professionals and researchers interested in understanding the procedures involved, to increasingly use reliable measures and instruments for a given studied fact.

The objective of this study was to develop and validate a care protocol for patients with pulmonary hypertension in intensive care units.

2. Methodology

This was a methodological study to validate the content of a care protocol for patients with pulmonary hypertension in intensive care, through the application of the Delphi technique, based on Spinola's theoretical framework (Spinola, 1984). Content validation was performed by expert evaluators on the subject, who analyzed the protocol items.

The data collection instrument was based on the researchers' experience and on the scientific literature, and a literature search was carried out in order to investigate the care inherent to patients with pulmonary hypertension admitted to ICUs. To this end, the international guidelines on pulmonary hypertension were consulted, as well as indexed journals – in particular, systematic reviews and randomized clinical trials – in the databases of the Latin American and Caribbean Health Sciences System (LILACS) and ScientificElectronic Library Online (SciELO); Medical LiteratureandRetrieval System Online, containing Index Medicus (Pubmed) by Medline. To search the databases, the strategy of identifying the Health Sciences Descriptors (DeCS/Bireme) and the Medical Subject Headings (MeSH/PubMed) was used, which identified the following general descriptors: “PulmonaryHypertension,”“ValidationStudies” and “ClinicalProtocols”; associated with specific descriptors: “criticalcare”and “complications.” Items related to patient care for pulmonary hypertension were determined (Messina, et al., 2015; Lapa et al., 2006; Galiè et al., 2009; Sales, et al., 2018; Ramos, et al., 2008; Castro & Rezende, 2009).

It should be noted that a new search for studies was carried out in the electronic databases between the months of September and December 2020, in order to update the variables of the data collection instrument.

The content validation of the instrument was carried out through the application of the Delphi technique, which consists of collecting data, and tabulating and evaluating a given phenomenon through the judgment of experts in the subject (Spinola, 1984).

Professional nurses and/or specialist physical therapistsand/or master’s and/or doctor’s degree holders working in the thematic area of this study were considered evaluators, to make up the judging panel. These evaluators were selected by analyzing the curricula submitted to the Lattes Platform on the website of the National Council for Scientific and Technological Development (CNPq) and through snowball sampling or network sampling, which consisted of asking the initial participants of the sample to indicate or recommend other participants who met the study selection criteria.

Health professionals (nurses and/or physical therapists), specialists, master’s and/or doctor’s degree holders, with at least three years of experience in caring for patients with pulmonary hypertension in intensive care units, and who agreed to participate in the study and to sign Free and Informed Consent forms, were included in the study.

Participants who did not meet the deadline for the evaluation of the data collection instrument that was stipulated for the rounds of this research were excluded.

For the 1st Delphi round, it was necessary to search for the evaluators between January and March 2021 due to the complexity of the theme. In April 2021, 20 health professionals (nurses and physical therapists) who met the study selection criteria were contacted by e-mail. Thirteen professionals agreed to participate, who received a Google Forms link containing the consent forms and the data collection instrument.

The evaluating participants answered the structured instrument anonymously. The evaluators were asked to return the instrument analyzed within 30 days. Due to the low number of evaluations obtained, evaluators who did not meet the deadline were reminded to answer the instrument. This was done between the months of May and June 2021, in order to obtain the maximum number of evaluations. However, 9 participants returned the completed instrument by July 31, 2021.

The evaluators were asked to provide information that characterized them and their individual and confidential opinion of the initial version of the instrument and related aspects. The evaluation of each variable of the instrument by the evaluators was performed using an opinion scale (Likert-type scale) with four points: 1 – "Completely Adequate"; 2 – "Adequate"; 3 – "Partially Adequate"; and 4 – "Inadequate".

For the 2nd Delphi round, after going through the first evaluation of the items by the specialists, the data collection instrumentwas restructured according to the evaluation and suggestions, and forwarded to the evaluators for the evaluation of each item regarding its content properties and the clarity of the statement. At this stage, the instrument was arranged in a dichotomous configuration, which consisted of having only two answer alternatives, YES or NO.

The following were evaluated for the items that made up each topic: objectivity (specific response); simplicity (demonstrates a single idea); clarity (specifically stated in a clear and simple way); pertinence (suggests exactness, appropriateness and relevance); and variety (without repetition of terms).

For the analysis of the results, the data wereentered and tabulated in Microsoft Excel, and quantitatively analyzed using a descriptive method (mean, median and standard deviation). In the 1st Delphi round, categories with scores of 4 and 3 on the Likert scale were considered, which led to a favorable consensus of 75% in the evaluations.

In the 2nd Delphi round, for the evaluation of each item of the topics, a YES consensus of greater than or equal to 80% among the participants was considered.

Quantitative variables were described using the mean and standard deviation (SD).The data were entered into a Microsoft Excel spreadsheet and sent to a statistician to carry out the analysis, using the SPSS 19® and R Core 4.1.1® software packages: openxlsx, psychometric, DescTools and text and spreadsheet editor: LibreOffice® 7.1.1.2.

The data obtained were analyzed by the equivalence between two or more evaluators using the Kappa coefficient. The Kappa index refers to an indicator to verify the adjusted agreement, characterizing a way of expressing the reliability of a study. This interpretation provides information about the proportion of agreement beyond that expected, ranging from “minus 1” (complete disagreement) to “plus 1” (complete agreement), and zero means readings taken at random.

A consensus level greater than 0.61 was established for the Kappa index, since it presents values between good and perfect agreement.

The content validity index (CVI) was calculated for each item of the questionnaire for each criterion (objectivity, simplicity, clarity, relevance and variety). The CVI was calculated by the percentage of experts who considered the item with the “YES” dichotomy for the criterion in question, with a minimum agreement of > 0.80.

3. Results

The study included 9 (100%) Brazilian nurses, 7 (78%) were female and 2 (22%) male, and of these, 7 (78%) were working in public institutions and 2 (22%) in private institutions.

Of the nine participants, 5 (56%) were specialists, 2 (22%) were master's degree holders, and 2 (22%) were doctor's degree holders. All reported clinical practice in ICUs and patients with PH.The time of practice ranged from 1 to 30 years, with a mean of 15, SD of 11.85, 1.45% for the first quartile, and 17.25% for the third quartile.

The age of the participants ranged between 24 and 49, with a mean of 36 and a median of 37. The first quartile corresponded to 25 and the third quartile to 56.

Regarding the place of work, 7 (78%) of the participants worked in the city of São Paulo and 2 (22%) worked in the countryside of São Paulo, as shown in Tables 1 and 2.

Table 1: Descriptive measures – ICU protocol.

	Age	Time since graduation(years)
Mean(Standard Deviation)	35.78(9.782)	11.854(10.582)
Minimum-Maximum	24-49	1-30
First quartile	25	1.458
Median	37	12
Third quartile	46	17.250

Source: Authors.

Table 2: Descriptive measuresof sociodemographic variables.

Gender:	n (%)
Female	7 (77.8%)
Male	2 (22.2%)
Profession:	n (%)
Nurse	9 (100%)
Education:	n (%)
Doctorate	2 (22.2%)
Specialization	5 (55.6%)
Masters	2 (22.2%)
Place ofpractice:	n (%)
Cardiology	1 (11.1%)
Hospital Municipal José de Carvalho Florence (SPDM)	1 (11.1%)
São Paulo	5 (55.6%)
Federal University of São Paulo (UNIFESP)	1 (11.1%)
UnoesteJaú	1 (11.1%)
Characterization:	n (%)
State	1 (11.1%)
Federal	5 (55.6%)
Municipal	1 (11.1%)
Private	2 (22.2%)

Source: Authors.

The proposed protocol was developed with 2 categories, 4 topics, and 23 items. The first topic refers to patient and family guidelines, the second to history assessment, the third to physical assessment, and the fourth to patient care.

Table 3: Descriptive measures of the suggestions.

Suggestion to change item 2.1 (Provide guidance and clarificationon the hospitalization and condition of the patient)	n (%)
0: No	7 (77.8%)
1: Yes	2 (22.2%)
Suggestion to change item 2.2(Provide guidance on the ICU structure and workdynamics)	n (%)
0: No	7 (77.8%)
1: Yes	2 (22.2%)
Suggestion to change item 2.3(Provide guidance on the importance of collecting exams and performing radiological exams, medications and infusions)	n (%)
0: No	8 (88.9%)
1: Yes	1 (11.1%)
Suggestion to change item 3.1(Assess acceptance and coping with the disease by the patient)	n (%)
0: No	8 (88.9%)
1: Yes	1 (11.1%)
Suggestion to change item 3.2(Check patient attendance at previous outpatient appointments)	n (%)
0: No	6 (66.7%)
1: Yes	3 (33.3%)
Suggestion to change item 3.3(Check if the patient has a therapeutic proposal)	n (%)
0: No	7 (77.8%)
1: Yes	2 (22.2%)
Suggestion to change item 3.4(Check if the patient takes the prescribed medications correctly and follows the recommendations of the health team)	n (%)
0: No	6 (66.7%)
1: Yes	3 (33.3%)
Suggestion to change item 4.1(Assess vital signs)	n (%)
0: No	8 (88.9%)
1: Yes	1 (11.1%)
Suggestion to change item 4.4(Constantly assess for signs of worsening)	n (%)
0: No	7 (77.8%)
1: Yes	2 (22.2%)
Suggestion to change item 5.1(Promote safety)	n (%)
0: No	8 (88.9%)
1: Yes	1 (11.1%)
Suggestion to change item 5.2(Administer prescription drugs)	n (%)
0: No	7 (77.8%)
1: Yes	2 (22.2%)

Suggestion to change item 5.3 (Optimize patient comfort)	n (%)
0: No	8 (88.9%)
1: Yes	1 (11.1%)
Suggestion to change item 5.4 (Perform hygiene care)	n (%)
0: No	8 (88.9%)
1: Yes	1 (11.1%)
Suggestion to change item 5.5 (Assessdiagnostic exams)	n (%)
0: No	6 (66.7%)
1: Yes	3 (33.3%)
Suggestion to change item 5.6 (Pay attention to the administration of vasoactive drugs)	n (%)
0: No	5 (55.6%)
1: Yes	4 (44.4%)
Suggestion to change item 5.10 (Ventilatory support)	n (%)
0: No	7 (77.8%)
1: Yes	2 (22.2%)
Suggestion to change item 5.11 (Enteral nutrition)	n (%)
0: No	7 (77.8%)
1: Yes	2 (22.2%)
Suggestion to change item 5.12 (Assess therapeutic proposal and discuss with the team)	n (%)
0: No	7 (77.8%)
1: Yes	2 (22.2%)

Source: Authors.

Cronbach's alpha coefficient (α) is a commonly used measure of reliability (the assessment of the internal consistency of questionnaires) for a set of two or more construct indicators. α values range from 0 to 1.0; the closer to 1, the greater the reliability between the indicators. The use of reliability measures, such as Cronbach's α, does not guarantee unidimensionalityof the questionnaire, but presumes that it exists (Bland, 1997; Rodríguez-Rodriguez and Reguant-Álvarez, 2020).

Note that all CVI and CVR (content validity ratio) measures were greater than 0.5, indicating that most evaluators agreed with the item. Removing item 5.3, the Cronbach's alpha becomes 0.575 with a 95% confidence interval ranging from 0.485 to 0.656 (Table 4).

Table 4: CVIandCVR.

	2: Partially Adequate		3: Adequate		4: Completely Adequate		CVI	CVR	α(i)*
2. Recommendations to the patient and thefamily	n	%	n	%	n	%			
2.1. Provide guidance and clarification on the hospitalization and condition of the patient. Answer possible doubts	-	-	3	33.3	6	66.7	1.000	1.000	0.489[0.380;0.587]
2.2 Provide guidance on the ICU structure and work dynamics	1	11.1	1	11.1	7	77.8	0.889	0.778	0.436[0.315;0.543]
2.3. Provide guidance on the importance of collecting exams and performing radiological exams, medications and infusions	-	-	3	33.3	6	66.7	1.000	1.000	0.507[0.402; 0.601]
3. Historyassessment									
3.1. Assess acceptance and coping with the disease by the patient	-	-	2	22.2	7	77.8	1.000	1.000	0.479[0.368; 0.578]
3.2. Check patient attendance at previous outpatient appointments	1	11.1	3	33.3	5	55.6	0.889	0.778	0.449[0.331;0.554]
3.3. Check if the patient has a therapeutic proposal	2	22.2	-	-	7	77.8	0.778	0.556	0.513[0.409; 0.606]
3.4. Check if the patient takes the prescribed medications correctly and follows the recommendations of the health team	1	11.1	3	33.3	5	55.6	0.889	0.778	0.459[0.345;0.563]
4. Physical assessment									
4.1. Assess vital signs	-	-	-	-	9	100	1.000	1.000	0.505[0.399; 0.599]
4.2. Perform cephalopodal physical assessment	-	-	-	-	9	100	1.000	1.000	0.505[0.399; 0.599]
4.3. Check for signs of deep vein thrombosis	-	-	2	22.2	7	77.8	1.000	1.000	0.523[0.421; 0.614]
4.4. Constantly assess for signs of worsening	1	11.1	2	22.2	6	66.7	0.889	0.778	0.444[0.326; 0.550]
5. Patient care									
5.1. Promote safety	-	-	1	11.1	8	88.9	1.000	1.000	0.485[0.375; 0.583]
5.2. Administer prescription drugs	1	11.1	2	22.2	6	66.7	0.889	0.778	0.543[0.446; 0.630]
5.3. Optimize patient comfort	1	11.1	2	33.2	6	66.7	0.889	0.778	0.575[0.485; 0.656]
5.4. Perform hygiene care	-	-	2	22.2	7	77.8	1.000	1.000	0.449[0.331; 0.554]
5.5. Assess diagnostic exams	-	-	6	66.7	3	33.3	1.000	1.000	0.501[0.395; 0.596]
5.6. Pay attention to the administration of vasoactive drugs	2	22.2	1	11.1	6	66.7	0.778	0.556	0.566[0.473; 0.648]
5.7. Identify devices, assess daily the need to remove invasive devices	-	-	1	11.1	8	88.9	1.000	1.000	0.485[0.375;0.583]
5.8. Be aware of possible complications	-	-	-	-	9	100	1.000	1.000	0.505[0.399; 0.599]
5.9. Hemodynamic assessment	-	-	-	-	9	100	1.000	1.000	0.505[0.399; 0.599]
5.10. Ventilatory support	-	-	3	33.3	6	66.7	1.000	1.000	0.524[0.422; 0.615]
5.11. Enteral nutrition	2	22.2	1	11.1	6	66.7	0.778	0.556	0.321[0.177;0.451]
5.12. Assess therapeutic proposal and discuss with the team	1	11.1	2	22.2	6	66.7	0.889	0.778	0.466[0.352; 0.567]

*Cronbach'salpha without the i-th item Source: Authors.

In the blocks of questions, for the most part, Cronbach's alpha remained below 0.5, where only item 3, Historical assessment, was acceptable. The other measures were all above 0.75.

The Cronbach's alpha of the questionnaire, considering the 9 participants, was 0.504 with a 95% CI ranging from 0.400 to 0.596, not indicating unacceptable consistency.

All CVR and CVI values were greater than 0.5, but Cronbach's alpha was low, with some authors indicating low internal reliability and others, moderate reliability. Table 4 shows the values of CVI, CVR and Cronbach's alpha, disregarding the i-th item; it was noted that Cronbach's alpha has the greatest increase when item 5.3 is removed.

Table 5 shows Cronbach's alpha considering only a few questions where item 3, Historical assessment, had the best Cronbach's alpha. Regarding the importance of the questions, the CVI and CVR showed high values, indicating the questions were kept.

Table 5: Global CVI, CVR mean andCronbach's alpha.

	Global CVI	CVR mean	Cronbach´s alpha [95% CI]
2. Recommendations to the patient and the family	0.963	0.926	0.300[-0.326; 0.658]
3. Historical assessment	0.889	0.778	0.725[0.542; 0.847]
4. Physical assessment	0.972	0.945	0.370[-0.048; 0.649]
5. Patient care	0.935	0.871	0.144[-0.115; 0.365]

Source: Authors.

The final construct remained with 4 topics and 23 items. Although Cronbach's alpha remained below 0.5 for item 3, the CVI and CVR showed high values, indicating the question was kept.

4. Discussion

The diagnosis of PH is often a major challenge. Hemodynamically, PH is defined by invasive measurements identifying mean pulmonary artery pressure (mPAP). In addition to diagnosing PH, invasive hemodynamic measurement allows for its classification according to the affected vascular territory. According to the pulmonary artery occlusion pressure (PAOP) value, PH is defined as pre- or post-capillary. (Hoeper et al.,2016; Simonneau et al., 2019)

The complexity of the hospital context, especially in adult ICUs, is an unusual and frightening environment for family members and companions. Most associate ICUs with suffering and death. With institutions increasingly concerned with promoting humanized care, carrying out a dialogue and promoting comprehensive listening and attention is essential for the appreciation and identification of beliefs, needs, expectations and anxieties of the families of hospitalized patients (Fettermann, et al., 2019; Gibaut, et al., 2013).

Humanization is still seen as a very complex set of attitudes and actions motivated by ethical, humanistic, social and holistic considerations. Today, the proposal for humanization in ICUs has a broader scope, encompassing everything from the physical environment,to relationships between health teams and the active participation of patients in their own treatment when possible. (Passos et al., 2015)

Intensive care units have different characteristics from other units, sincethey are environments where much of the information about patients is obtained through monitoring machines or medical records. This ends up interfering with communication between family members and professionals and with humanization of care (Rezende, et al., 2013).

Corroborating this trend towards humanized care, the evaluators of this protocol considered the items related to guidance and clarification to patients and families regarding the hospital environment and specifically the ICU, and regarding the proposed treatment, to be relevant. The importance of involving patients and families in each stage of their treatment is perceived.

Welcoming families and companions and patients themselvesis part of the National Humanization Policy (PNH), which has the role of ensuring that citizens are listened to carefully so that they have adequate access to all units of the public health system, and are able to receive clarification of their doubts and alleviation of their fears and anxieties, with due attention to their needs, respecting their rights (Brazil, Humaniza SUS, 2004).

Welcoming is a fundamental factor to ensure the well-being of patients during hospitalization, since individuals are deprived of their daily activities and end up being subjected to restrictive routines imposed by strangers. This condition often causes discomfort, anguish, fear and pain, making patients more vulnerable to other health problems. The presence of family members or acquaintances as companions or as visitors can provide comfort, reinforce patients' sense of security, and improve the acceptance of treatments proposed by health teams (Da Silva et al., 2022; Galan Gonzalez-Serna, et al., 2017; Neves, et al., 2018).

Unfortunately, the possibility of having companions in ICU environments is not a reality in most Brazilian institutions, although the advantages for patients and their families are now perceived. For this reason, many institutions, based on scientific evidence, have sought to make the necessary adaptations for this to occur (Moraes, et al., 2021).

Nurses are responsible for providing comprehensive and continuous care to patients in the most diverse serious situations in ICUs, carrying out comprehensive evaluations in a systematic way, to determine the appropriate use of information, and human, material and physical resources, in the care of the sick (dos Santos Junior, 2021).

The nursing process has represented the main methodological model for the systematic performance of professional nursing practice. Anamnesis and physical examination, two stages of this process, are essential and allow nurses to perform diagnosis, plan nursing actions, monitor, and evaluate the patients 'evolution (dos Santos, et al., 2018).

The physical examination constitutes the first phase of the nursing process and requires consistent development of clinical reasoning. With this, professionals identify patient's' needs and offer care plans based on human responses in order to select the appropriate interventions and evaluate the achieved results (Xavier, et al., 2018; Carvalho, et al., 2017).

The history assessment performed by nurses is covered in topic 3 of the protocol proposed in this study, and is a fundamental step for a quality nursing process. No changes were suggested by the evaluators, who judged that they were relevant issues to compose the care protocol for patients with PH. Items such as knowledge of the patient regarding the disease itself, adherence to treatment, attendance at outpatient consultations, and knowledge of the therapeutic proposal proved to be fundamental items in the protocol.

With the presence of technology in the various health sectors in Brazil and in the world, especially in ICUs, nursing professionals face a great challenge, given the need to incorporate technology into patient care and master the scientific basis on which its use is based, and at the same time meet the clinical needs of patients (Amorin & Silvério, 2003; Narula, et al., 2018; Herrle, et al., 2011).

Humanization of care is not an easy task, and in order for it to occur, individualized attitudes are necessary, which often goes against the entire technological system that has been dominant up to now (de Vargas & Braga, 2006; Pereira et al., 2019; de Lima, et al., 2020).

A study carried out in 2015 evaluated 208 nursing students regarding the application of physical examination skills in clinical practice during their undergraduate studies. It was found that of the 126 skills taught, only 5 were used more frequently, and that some essential skills that should be performed routinely with all patients were rarely performed (Douglas, et al., 2015; Giddens, 2007).

This study revealed that performing a good physical examination is essential for clinical diagnosis, reducing the costs of laboratory tests and imaging diagnoses, in addition to strengthening nurse-patient relationships. It showed that the

establishment of measures for continuing education positively impacts levels of knowledge, practice and care management (Gharaibeh, et al., 2019).

Item 3.3 of the PH patient care protocol refers to deep vein thrombosis (DVT). This is characterized by the presence of thrombi that obstruct the deep veins, mainly of the lower limbs, and is caused by a combination of the three components of Virchow's triad: endothelial injury, venous stasis, and hypercoagulability. This occlusion of the deep venous system can be partial or total, with the main complication being the detachment of the thrombus, with the formation of emboli that can obstruct other arteries, especially the pulmonary artery, resulting in pulmonary embolism. In addition, post-thrombotic syndrome occurs as an important complication of the disease, which appears in up to 50% of patients with DVT. This syndrome is characterized by the chronicity of the symptoms of the disease and is diagnosed from the sum of signs (pre-tibial edema, hyperpigmentation, erythema, venous ectasia) and symptoms (cramps, pain, heaviness, pruritus), by the scale of Villalta (Charlo, et al., 2020; Brazilian Society of Angiology, 2015; Brandão, et al., 2018; Maia, et al., 2014).

There is a high incidence of DVT. In 2018, a study showed that it occurred in the general population in 5 cases per 10,000 individuals annually, and in Brazil around 0.6 per 1,000 inhabitants annually. Proximal type DVT evolves to pulmonary embolism in 46% of cases, and if left untreated, it can progress to death in 4% of cases. In Europe, rates reach 600,000 cases of deep vein thrombosis and pulmonary embolism annually. In the United States, 300,000 cases of thrombosis are registered per year, with DVT being the third most common cause among cardiovascular pathologies. In Brazil, studies have shown 122,096 hospitalizations for thrombosis, recorded in 2014, and a decrease in this rate to 113,817 in 2015 (Brandão, et al., 2018; Couto, et al., 2017).

Deep vein thrombosis mortality occurs in about 25% of cases, due to organ impairment, with sudden death being the first symptom, which affects 10% to 30% of the North American population in the first 30 days after diagnosis. It presents acquired risk factors, highlighting surgeries and immobilizations, mainly related to hospitalization, a factor that places DVT as the main cause of death in hospital environments, since the pathophysiological evolution time is directly proportional to the immobilization time of the individual (Alves, et al., 2015; Farhat, et al., 2018).

The reported cases emphasize the importance of thrombus prophylaxis, especially in hospitalized patients, who are an important risk group in the development of the pathology. Prophylaxis can be performed using elastic compression stockings, as well as anticoagulation in these patients, according to medical recommendations (Farhat, et al., 2018).

Critically ill patients should receive differentiated attention, not only because of their high risk, but also because of the multiplicity of variables that can influence the decision regarding prophylaxis. Often, the definition of an action can become extremely difficult, involving specific considerations in relation to the risk of bleeding events (Ribeiro, et al., 2006).

Non-adherence to treatment after hospital discharge is one of the most important causes of treatment failure (Macete & Borges, 2020; Rocha, et al., 2017). Topic 2 of the protocol is entirely dedicated to the acceptance and knowledge of patients about their disease and treatment, and proved to be fundamental after evaluation by experts.

There are several factors that contribute to lack of adherence to treatment. They are age, education level, socioeconomic level, financial difficulties, therapeutic regimens, difficulty in accessing the health system, and chronicity of the disease (Ministry of Health. Health Care Secretariat 2014; Rocha, et al., 2017).

The best intervention for good adherence to treatment is education, especially if the educational proposal is centered on beliefs and concerns about the health conditions and treatment of patients (Girotto, et al., 2013; Machado, et al., 2016).

Pharmacological treatment is essential in controlling the possible clinical manifestations that may arise. Non-adherence to pharmacological treatment is associated with symptoms, worse prognoses, recurrent hospitalizations, high costs, and unnecessary adjustments in medical prescriptions. Safety, efficacy and adherence to pharmacological treatment are important challenges in care practice and require effective interventions from entire multidisciplinary teams in which

pharmacists are inserted, and these professionalscan make a significant difference by participating in decision-making and treatment counseling (Neves, et al., 2020).

Counseling is a process of exchanging information between patients and health teams, in which professionalsprovide guidanceto patients on various aspects of health care. This activity brings great benefits to patients and provides greater recognition of the professionals involved; patients become able to understand the need for the suggested treatment to maintain their health and well-being (Ferreira & Caprara, 2018).

Non-adherence to treatment can generate numerous psychological disorders, such as emotional problems, generalized anxiety, and depression. An interdisciplinary look at the context of non-adherence is necessary, reinforcing the importance of understanding and individualized approaches to patients (Butler et al., 2004; Fiuza, et al., 2013).

With greater access to technology, telemedicine has helped in health care and works as a strategy to improve adherence to pharmacological and non-pharmacological treatments (Velasco, et al., 2020; Evans et al., 2016; Goldstein et al., 2014).

Studies emphasize that personalized telemonitoring helps to improve adherence, since virtual systemsintegrate users on a full-time basis, providing feedback to professionals who are responsible for patients (Boyne et al., 2014).

Diagnosis of PH goes through a series of steps,including clinical examinations, laboratory tests, electrocardiograms, and imaging tests (Galie et al., 2016).

Imaging tests play a fundamental role in the diagnosis and treatment of PH. Knowledge on the part of nurses about this subject becomes a differential for quality treatment of patients with PH. The protocol proposed in this study addresses this issue in item 5.5, which demonstrated good acceptability by the evaluators (Pazello & Camarozano, 2018).

Chest radiography provides an overview of the lungs and pulmonary vasculature in general, and, despite its limited value in early stages, it is frequently utilized in PH. It may show central pulmonary artery dilatation (particularly of the descending portion of the right pulmonary artery), scarcity of peripheral blood vessels, and increase in the cardiothoracic ratio due to dilation of the right heart cavities, with effacement of the retrosternal space on lateral radiography. All these changes are consistent with PH. Moreover, chest radiography may show the presence of other lung diseases, such as fibrosis or emphysema, which may also be responsible for PH (Galie et al., 2015; Schmitt-Opitz & Ulrich, 2018; Hartopo, et al., 2017; Gopalan, et al., 2017; Johns, et al., 2018; Renapurkar, et al., 2017).

Echocardiography is a fundamental non-invasive exam to assess the potential consequences of PH at the cardiac level and to estimate pulmonary artery pressure (PAP) with continuous Doppler through the modified Bernoulli equation (4 x [tricuspid regurgitation rate]^2 + central venous pressure), and should be performed with patients in apnea (Galie et al., 2016; Schmitt-Opitz & Ulrich, 2018; Yandrapalli et al., 2018; Hartopo, et al., 2017; Gopalan, et al., 2017). According to the echocardiographic probability obtained, the additional investigation plan is established for a diagnostic approach (Galie et al., 2016)

Lung scintigraphy is useful in the evaluation of patients with PH. Among the advantages of this exam are that it is easily interpretable, uses relatively low doses of radiation without the need to use intravenous contrast agents, and is inexpensive. One of the limitations of this technique is the inability to detect the anatomic location of the disease (Galie et al., 2016; Schmitt-Opitz & Ulrich, 2018; Yandrapalli et al., 2018; Memon, et al., 2016; Gopalan, et al., 2016; Gopalan, et al., 2017; Johns, et al., 2018; Renapurkar, et al., 2017).

Pulmonary computed tomography angiography (CTA) provides information about the pulmonary vasculature and the size of the cardiac chambers and allows the identification of PH, anatomically localizing the changes, although it cannot safely rule out this pathology. This exam allows precise image resolution (0.5 mm) to be obtained with a short apnea time (3-5 seconds), and is therefore easily performed even in patients with dyspnea (Galie et al., 2016; Schmitt-Opitz & Ulrich, 2018;

Yandrapalli et al., 2018; Gopalan, et al., 2016; Hartopo, et al., 2017; Wilkens et al., 2018; Gopalan, et al., 2017; Johns, et al., 2018).

Cardiac magnetic resonance imaging (MRI) is the exam of choice to assess the size, morphology, and function of the right ventricle (RV), and can be used in the diagnosis of PH and in the assessment of obstructive pulmonary arterial disease. It has a sensitivity and specificity of 83.1% and 98.6% at the lobar level and 87.7% and 98.1% at the segmental level, respectively (Galie et al., 2016; Schmitt-Opitz & Ulrich, 2018; Johns, et al., 2018).

The administration of vasoactive drugs (VADs) is an extremely important competency performed by nursing teams and supervised by nurses. The protocol of this study includes this important competency in item 5.6. It is known that vasoactive drugs are among the most used drugs in intensive care units (Morais, et al., 2020). They can optimize cardiac output and systemic and pulmonary vascular tone, due to their peripheral, pulmonary, cardiac and renal effects, with vasoconstriction, inotropism, chronotropism, and bronchodilation, among others. They can restore blood flow to vital organs in states of circulatory shock (da Fonseca, 2001; Udesen et al., 2020),since they have rapid and potent action, improving the prognosis and survival of patients. However, their use is associated with numerous adverse reactions, making it necessary to use them with caution and with hemodynamic and laboratory monitoring (Wolfe et al., 2018; Jentzer, et al., 2015), because the response in alpha and beta receptors is directly related to the applied dose (Udesen et al., 2020).

Allied to the administration of VADs is hemodynamic monitoring. This subject, also contemplated in the protocol, is of paramount importance and must be widely known by nursing teams. Hemodynamic monitoring refers to invasive monitoring of the arterial and venous system, used to measure intracardiac, intrapulmonary, and intravascular pressures and to determine the effectiveness of therapy. Despite the rapid advancement of non-invasive monitoring techniques, invasive hemodynamic monitoring is essential in ICUs (da Silva et al., 2019; Ramos et al, 2008; Dias et al., 2006)

Invasive hemodynamic methods are also essential in defining PH. Recent studies have shown that, even with lower mPAP values, there is an increase in mortality rates (Maron et al., 2016) In December 2018, a consensus resulting from the 6th World Symposium on Pulmonary Hypertension redefined PH to a situation where mPAP is greater than 20 mmHg and pulmonary vascular resistance is greater than or equal to 3 Wood units (Calderaro, et al., 2019; Simonneau et al., 2014; Simonneau et al., 2019).

Professionals must be able to select and carry out the most appropriate monitoring methods according to the individual needs of patients, considering the risk-benefit balance of the techniques. Monitoring data mean nothing if they are not added to physical findings and critically analyzed by nurses (Da Silva et al., 2019; Azevedo & Oliveira, 2013).

Critically ill patients with invasive monitoring are exposed to additional risks of complications such as air embolisms, hemorrhages, incorrect placement of catheters, tissue damage, or hemodynamic compromise resulting from the introduction of foreign bodies. It is essential that nurses use aseptic techniques to maintain systems and continuously assess patients' response to equipment; look for inflammatory signs at catheter insertion sites; and create a routine to replace them (Dias et al., 2006; Azevedo & Oliveira, 2013).

Knowledge about invasive hemodynamic monitoring helps to develop clinical decision-making skills, moving from the simple recording of vital signs to the interpretation and analysis of that information, in order to formulate appropriate nursing care plans for individuals. Adequate preparation of health professionals for the care of patients with these invasive devices in order to develop a more associative and evidence-based care is extremely necessary for quality care (Da Silva et al., 2019).

The use of patient care protocols systematizes nursing care, andpromotes consistency in care actions so that more humane and quality care is provided (Santos, et al., 2016; Silva, et al., 2012).

5. Conclusion

The protocol for care of patients with pulmonary hypertension was structured with 4 topics and 23 items, aiming to be a practical instrument that guarantees patient safety and the quality of care provided in conjunction with technological advances.

It is believed that the protocol will help multidisciplinary teams to promote safe, accurate and efficient care for patients with pulmonary hypertension in intensive care units.

This study aimed to guide the clinical practice of health professionals in the care of patients with pulmonary hypertension. It is believed that further studies will be able to carry out clinical validation to evaluate the efficiency of the variables that make up the constructed and validated protocol.

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