Construction and validation of standard operating protocol of prone positioning in Intensive Care Unit

RESUMO I Objetivo: Construir e validarum protocolo operacional padrão da técnica prona em uma Unidade de Terapia Intensiva. Método: Pesquisa metodológica organizada em duas etapas: construção do protocolo e validação do conteúdo e aparência. A busca na literatura ocorreu na base de dados eletrônicas: portal capes, PUBMED, BVS, MEDLINE, LILACS, BDENF. Após levantamento bibliográfico para a construção o POP foi avaliado por juízes. Análise foi realizada pelo Índice de Validade do Conteúdo (IVC), considerando aceitável acima de 80%. A coleta de dados ocorreu de fevereiro a junho de 2020. Resultados: POP foi composto por 76 itens, dividido em quatro etapas, 24 juízes fizeram parte da amostra para validação. Os itens tiveram IVC maior que 90% para categorias todos e não grupo, o grupo específico a concordância foi maior que 90% em 88,5% dos itens. Conclusões: Avaliação dos juízes determinou validação quanto aparência e conteúdo do POP de prona com uma rodada. **Descritores:** Decúbito ventral; Unidade de Terapia Intensiva; Equipe de Assistência ao Paciente; Cuidados de Enfermagem; Cuidados Críticos.

ABSTRACT | Objective: To build and validate a standard operating protocol for the pronetechnique in an Intensive Care Unit. Method: Methodological research organized in two stages: construction of the protocol and validation of content and appearance. The literaturesearchtookplace in theelectronicdatabase: capes portal, PUBMED, BVS, MEDLINE, LILACS, BDENF. After a bibliographical survey for the construction of the SOP, it was evaluated by judges. Analysis was performed using the Content Validity Index (CVI), consideringacceptableabove 80%. Data collectiontookplacefromFebruarytoJune 2020. Results: POP consistedof 76 items, dividedinto four stages, 24 judgeswerepartofthe sample for validation. The itemshad CVI greaterthan 90% for allcategoriesandnot for thegroup, thespecificgrouptheagreementwasgreaterthan 90% in 88.5% oftheitems. Conclusions: The judges assessment determinedvalidationregardingtheappearanceandcontentoftheone-round prone SOP.

Keywords: Prone Position: IntensiveCareUnits: PatientCare Team: NursingCare: CriticalCare

RESUMEN | Objetivo: Construir y validar un protocolo estándar de operación para la técnica de decúbito prono en una Unidad de Cuidados Intensivos. Método:Investigación metodológica organizada endos etapas: construccióndel protocolo y validación de contenido y apariencia. La búsqueda bibliográfica se realizóenla base de datos electrónica: portal capes, PUBMED, BVS, MEDLINE, LILACS, BDENF. Luego de unlevantamiento bibliográfico para laconstruccióndel POE, fueevaluado por jueces. El análisis se realizó mediante el Índice de Validez de Contenido (IVC), considerándoseaceptable por encima del 80%. La recolección de datos se llevó a cabo de febrero a junio de 2020. Resultados:el POP estuvocompuesto por 76 ítems, divididos encuatro etapas, 24 juecesformaron parte de lamuestra para lavalidación. Los ítemstuvieron CVI superior al 90% para todas lascategorías y no para el grupo, el grupo específico laconcordanciafue superior al 90% enel 88.5% de losítems. Conclusiones: La evaluación de losjueces de terminó la validación en cuanto a la apariencia y el contenido del SOP de una ronda en decúbito prono.

Palabras claves: Posición Prona; Unidades de Cuidados Intensivos; Grupo de Atención al Paciente; Atención de Enfermería; Cuidados Críticos

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INTRODUCÃO

Acute respiratory distress syndrome (ARDS) has high morbidity and mortality, one of the ways that help its treatment is the positioning of the patient in bed, more specifically in the prone position (ventral). This is a maneuver used to recruit alveoli in patients with this syndrome, indicated for moderate and severe cases that present a relationship between partial arterial pressure (PaO2) and fraction of inspired oxygen (FiO2) <150, with the objective of treating severe hypoxemia, the position promotes the improvement of gas exchange as it provides a more homogeneous supply of lung volume (1).

The PROSEVA study (The Proning Severe ARDS Patients), showed the benefit of the prone position in patients hospitalized with severe ARDS, the mortality of these patients was significantly lower in the prone group than in the supine group, other parameters evaluated such as the PaO2/FiO2 ratio, positive end-expiratory pressure (PEEP) and FiO2 also showed lower values in the first group compared to the second, the rate of successful extubation was higher in the prone group. (2)

The prone position offers clinical benefits and reduced mortality (3), presents an improvement in hypoxemia in 70% of cases, it is considered an easy and inexpensive technique, but it is not free of complications. (4) The technique is performed manually and does not require special equipment, but it must be performed by a trained team with safety measures to avoid associated complications. (5)

Prone positioning is associated with an increased risk of endotracheal tube obstruction (ETT) and pressure injuries (PI). PI were the most frequent adverse event (34%), followed by ventilator--associated pneumonia (21.4%), OTT obstruction, (14.6%), loss of venous access (10.9%), pneumothorax (5.8%) and OTT displacement (3, 7%). (6) Thus, performing the procedure in an organi-

zed and systematic way brings benefits to patients. The construction of a standard operating procedure (SOP) aims to systematize processes, standardize and provide quality care, helps to prevent and reduce risks and damage to health, contributing to standardized and safe care. (7)

Therefore, the guiding question of this study is: does the standard operating protocol (SOP) for prone positioning in intensive care that will be proposed in this study have content validity? For this, the objective of this study was to construct and validate, in terms of appearance and content, a standard operating protocol for the prone technique in an Intensive Care Unit (ICU).

METHOD

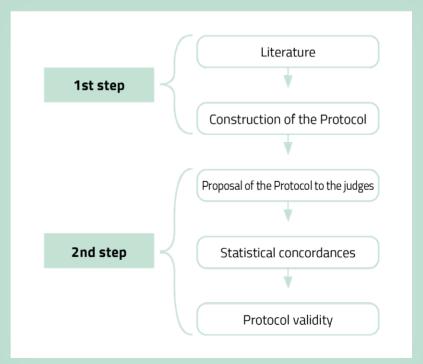
This is a methodological study, as it

is a study designed to verify new methods and procedures adopted in a given space. Data collection took place from February to June 2020, in two stages, in an ICU of a municipal hospital in Curitiba, Paraná.

To achieve the objective of this research, it was divided into two stages; the first, which took place from February to March 2020 and consisted of a bibliographic review for the construction of the protocol and the second, from April to June 2020, in its proposal to the judges for validation by content and appearance. Figure 1 demonstrates how the methodological operationalization was developed.

Step 1 comprised the literature review for the construction of the standard operating protocol. The literature search was carried out, from February to March 2020, in the electronic data-

Figure 1 - Methodological operationalization of the construction and validation of the standard operational protocol. Curitiba, Paraná, Brazil, 2020.



Source: The authors, 2020

bases: Portal Capes, PUBMED, National Library of Medicine, Portal of the Virtual Health Library (VHL), MEDLINE- International Literature in Health Sciences, LILACS- Latin American and Caribbean Literature in Health Sciences and BDE-NF- Nursing Database (BDENF), and gray literature. Using the descriptors in health sciences (DECS) prone, intensive care unit and patient care team.

To carry out the search in the databases, the inclusion criteria for the first stage were defined as: articles published in full, electronically available in Portuguese, English, Spanish, dissertations and/or theses and care protocols, with the theme in question. No distinction of level of evidence. Duplicate publications and articles without abstracts were excluded.

After compiling the information found in the articles and support materials, a protocol was described in four parts, namely: first - before prone (13 specific items for nursing technicians and nurses, 10 for nurses only, five for physicians, five for physiotherapists); second - prone maneuver (three for nurses, four for physicians, two for physiotherapists, three for nursing technicians and 12 for all professionals); third - patient in prone position (six specific items for nurses, five for physicians and five for physiotherapists); fourth and last stage - return to the dorsal position (three items for all professionals to perform). The SOP with 76 items was presented to the judges for the validation stage (second stage).

In step 2, which comprised the SOP proposal to the judges for validation of content and appearance, a semi-structured form was constructed to evaluate the elaborated protocol, in which the items were evaluated according to the criteria suggested by Pasquali, regarding objectivity, simplicity, clarity, accuracy, appearance, scientific writing, sequence and content. Data collection for this step was from April to June 2020.

The physical structure of the ICU consists of 21 beds, divided into two environments, with a profile of mostly clinical care, with occasional surgical hospitalizations. This sector has a multidisciplinary team made up of: 62 nursing technicians, 16 nurses, 18 doctors, 10 physiotherapists.



The prone position offers clinical benefits and reduced mortality, presents an improvement in hypoxemia in 70% of cases, it is considered an easy and inexpensive technique, but it is not free of complications.



The sample for content validation (second stage) consisted of 24 judges, who were selected through intentional sampling. As inclusion criteria for this stage, the following were adopted: professionals who perform prone technique on the patient, nurses, physicians, physiotherapists and nursing technicians who agreed to participate in the research and who work in the ICU in question. All professionals who do not work in direct patient care, who were on vacation or on leave were excluded.

Each item of the first version of the SOP was appreciated by the committee of judges regarding the criteria of objectivity, simplicity, clarity, precision and appearance, based on a Likert Scale with the following indicators: 1 - totally disagree, 2 - partially disagree, 3 - partially agree, 4 - totally agree. In addition, the instrument contained a place for suggestions.

As a way of evaluating the quality of the proposed instrument, the Content Validation Index (CVI) was used, which consists of calculating the proportion of evaluators who agreed or wholly agreed on the points evaluated in the questionnaire (76 questions). (8) Also, the general CVI was calculated, which consists of the general number of answers 3 - I agree or 4 - I totally agree in relation to the number of answers. Then, the proportion of identical responses among raters was calculated, as it was not possible to calculate a coefficient of agreement. To verify the validity of the instrument in terms of content, an agreement value > 80% was chosen between the judges, for each round, if the percentage was not reached, more than one round would be necessary. The judges had a period of 30 days to finalize such analysis.

The collected data were organized into spreadsheets using Microsoft Office Excel 2019 and exported to the R version 4.0.2 software used to develop the analysis. (9) Descriptive statistics were used to present the data, using simple and absolute frequencies.

The research complied with the ethical precepts of Resolution No. 466/12 of the National Health Council and was approved by the Research Ethics Committee of the Municipal Health Department of Curitiba - SMS, with CAAE



- 28620420.2.0000.0101 under opinion No. 3.851.135.

RESULTS

The content validity stage was carried out by a committee formed by 24 judges, six nurses, seven nursing technicians, five physicians and six physiotherapists. With a mean age of 35.5 years (standard deviation of 5.6), 79.2% (n=19) were female, 76.5% (n=13) of the professionals who answered about their training had specialization, 11.8% (n=2) had a master's degree and 11.8% had only a degree, the seven participants who did not respond were nursing technicians, 80% (n=12) worked in intensive care. The average time since training was 9.9 years and working in the profession was 9.6 years, the average time working in an emergency was 8.5 years, and in the ICU 6.5 years.

The analysis of the results will be presented in general and in stages, as proposed in the SOP, as follows: first before prone, second - prone maneuver, third - patient in prone position, fourth and last - return to position dorsal.

Regarding the CVI of the total SOP questions (n=76) it is noted that for 71% (n=54) of the questions, all professionals agreed. Since when the questions were not from the specific group, the lowest percentage of professionals who agreed was 90.9% (n=22); when they were in the specific group, it was 83.3%, and this occurred for the group of nurses and physiotherapists. However, it is important to note that 83.3% represents that five of the six professionals agreed (in this case, both nurses and physiotherapists had six respondents), that is, only one disagreed. When evaluating all questions together, the lowest percentage of agreement was 91.7%. This happens because the sample size is no longer a specific group, but all respondents.

Regarding the CVI of the total POP questions (n=76) it is noted that for 71%

Table 1. Content Validity Index by specific and non-specific group of the first stage of prone SOP. Curitiba, Paraná, Brazil, 2020.

CATEGORY	OUECTIONS	FIRST STEP					
	QUESTIONS	Not from the group		Group		All	
		%	n	%	n	%	n
	1	100	11	100	13	100	24
	2	100	11	92,3	12	95,8	23
	3	100	11	92,3	12	95,8	23
	4	100	11	84,6	10	91,7	22
	5	100	11	92,3	12	95,8	23
	6	100	11	100	13	100	24
NUR OR NURSING TEC.	7	100	11	92,3	12	95,8	23
	8	100	11	100	13	100	24
	9	100	11	100	13	100	24
	10	100	11	100	13	100	24
	11	100	11	100	13	100	24
	12	90,9	10	100	13	95,8	23
	13	100	11	100	13	100	24
	14	100	18	100	6	100	24
	15	100	18	100	6	100	24
	16	100	18	100	6	100	24
	17	100	18	100	6	100	24
NUIDCE	18	100	18	100	6	100	24
NURSE	19	100	18	100	6	100	24
	20	100	18	83,3	4	95,8	23
	21	100	18	83,3	4	95,8	23
	22	100	18	100	6	100	24
	23	100	18	100	6	100	24
	24	94,7	18	100	5	95,8	23
	25	94,7	18	100	5	95,8	23
PHYSICIAN	26	100	19	100	5	100	24
	27	94,7	18	100	5	95,8	23
	28	100	19	100	5	100	24
PHYSIOTHERAPIST	29	94,4	17	100	6	95,8	23
	30	100	18	100	6	100	24
	31	100	18	83,3	5	95,8	23
	32	100	18	100	6	100	24
		100	18	100	6	100	24
Source: Authors, 2020.							

(n=54) of the questions, all professionals agreed. Since when the questions were not from the specific group, the lowest percentage of professionals who agreed was 90.9% (n=22); when they were in the specific group, it was 83.3%, and this occurred for the group of nurses and physiotherapists. However, it is important to note that 83.3% represents that five of the six professionals agreed (in this case, both nurses and physiotherapists had six respondents), that is, only one disagreed. When evaluating all questions together, the lowest percentage of agreement was 91.7%. This happens because the sample size is no longer a specific group, but all respondents.

When analyzing the second stage, which refers to prone positioning, the average CVI of the four professions in the specific groups was 100% for all items. In the items that were general due to being a result of multiprofessional action, the agreement ranged from 95.8% (n= 23) to 100% (n= 24), as shown in table 2.

The third stage of the prone position, called patient in the prone position, considering each profession in its specific questions, the average CVI for nurses was 94.4% (questions one to six), with four questions with 100% (n= 6) of agreement (Items 1, 3, 5, 6) and question two and four scored 83.3% (n= 5), being the lowest score. Questions related to the physician (question 7 to 11) had an average CVI of 100%. In the specific part of the physiotherapists, the average CVI was 96.7%, with questions 13 and 16 with 100% (n= 6) of agreement and question 12 with 83.3% (n= 5), as shown in the table 3.

When analyzing the fourth and last stage, return to normal position, which cover all professions, the average CVI was 98.6%, items one and three with 100% (n=24) and item two with 95.8% (n=23) of agreement.

When considering responses from the category everyone and not from

Table 2. Content Validity Index by specific and non-specific group of the second stage of prone SOP. Curitiba, Paraná, Brazil, 2020

Stage of profit 2011 Cartaba, Farana, Diazin, 20201							
CATEGORY	QUESTIONS			SECOND	SECOND STEP		
	QUESTIONS	Not from the group		Group		All	
		%	n	%	n	%	n
NURSE	1	94,4	17	100	6	95,8	24
	2	94,4	17	100	6	95,8	24
	3	100	18	100	6	100	24
PHYSICIAN	4	100	19	100	5	100	24
	5	100	19	100	5	100	24
	6	100	19	100	5	100	24
	7	100	19	100	5	100	24
PHYSIOTHERAPIST	8	100	18	100	6	100	24
	9	100	18	100	6	100	24
NURSE TECHNICIAN	10	100	13	100	11	100	24
	11	100	13	100	11	100	24
	12	100	13	100	11	100	24
	13					100	24
	14					95,8	23
MULTIPROFESSIONAL	15					100	24
	16					100	24
	17					100	24
	18					100	24
ACTION	19					100	24
	20					100	24
	21					95,8	23
	22					95,8	23
	23					100	24
C A.uk 2020						100	24
Source: Authors, 2020.							

the group, all items had a CVI >90%. When considering a specific group, 88.5% of the items had a CVI > 90%, and 100% had a CVI > 80%.

Regarding the general aspects of

the POP, one participant did not respond and the others agreed with 100% of the criteria of objectivity, simplicity, clarity, precision and appearance.



DISCUSSION

The construction of a SOP aims to systematize processes to provide safer patient care(7), it is appointed as a management tool that supports the nurse's decision-making, recommends how the organization of the nursing service should happen, allows all workers to provide standardized care for the patient within the technical and scientific principles, has an educational purpose as it collaborates with the elimination of distortions acquired in practice, providing greater safety in the performance of procedures(10).

The use of the prone technique suits the need for a specific POP, since its frequency is not daily in ICUs in general. However, the number of patients placed in the prone position has been increasing, data collected through electronic medical records in the years 2017 and 2018, indicate that 28 patients were placed in the prone position in the first 6 months of the year 2017 compared to the next year where they occurred 33 prone maneuvers (5) as an early treatment for patients affected by the disease(11).

Knowing the benefits of prone positioning in patients with ARDS, the focus is on having a well-trained team that follows a streamlined process to produce the desired effects and minimize potential complications of prone positioning, therefore, following the guidelines of the interdisciplinary guideline on prone positioning it is considered necessary that the team that performs the technique be multidisciplinary and that all team members are involved in the procedure from planning, execution, evaluation and recovery (5).

In the construction of the prone SOP, the activities were divided between the nursing team (comprising both nurses and nursing technicians), nurses, nursing technicians, physiotherapists and physicians due to the need

Table 3. Content Validity Index by specific and non-specific group of the third stage of prone SOP. Curitiba, Paraná, Brazil, 2020.

CATEGORY	QUESTIONS	THIRD STAGE						
		Not from the group		Group		All		
		%	n	%	n	%	n	
	1	100	18	100	6	100	24	
	2	100	18	83,3	5	95,8	23	
NUIDCE	3	100	18	100	6	100	24	
NURSE	4	100	18	83,3	5	95,8	23	
	5	100	18	100	6	100	24	
	6	100	18	100	6	100	24	
DOCTOR	7	100	19	100	5	100	24	
	8	100	19	100	5	100	24	
	9	100	19	100	5	100	24	
	10	100	19	100	5	100	24	
	11	100	19	100	5	100	24	
PHYSIOTHERAPIST	12	100	18	83,3	5	95,8	23	
	13	100	18	100	6	100	24	
	14	100	18	100	6	100	24	
	15	100	18	100	6	100	24	
		100	18	100	6	100	24	
Source: Authors 2020								

Source: Authors, 2020

to organize the service and understand the roles. However, it is suggested that the executors of each phase are responsible for carrying out the formal registration in the patient's medical record to obtain accurate information, and that the multidisciplinary team as a whole is responsible for the patient and his/her care before the prone maneuver, in view of this, the need arose for each SOP item to be evaluated by the specific group and the non-specific group.

The search in the literature made it possible to identify the most frequent adverse events and thus list all the

items necessary for an effective and safe prone maneuver. Therefore, the SOP was written using a structure of four moments of the maneuver, describing its step-by-step for each professional involved.

Prone positioning is absolutely contraindicated in spinal instability, multiple unstable fractures, intracranial hypertension (>30mmHg), severe hemodynamic instability, MAP<65mmHg with vasopressor medication, deep venous thrombosis, treated in less than 48 hours, and pregnancy. And relative contraindication tracheal surgery or sternotomy in the last 2 weeks previous chest drain, recent ophthalmic surgery or maxillofacial surgery in the last 15 days, hemoptysis; recent pacemaker, distended abdomen, abdominal stoma, intestinal ischemia, recent abdominal surgery, burns in more than 20% of the body surface(12,13).

The first stage of the prone technique consists of a set of pre-maneuver precautions aimed at optimizing the time for performing the maneuver and minimizing intercurrences(4). Among the precautions, the need for a multidisciplinary team to be available to perform the technique stands out; pause in the diet by nasoenteric tube; organization and manufacture of cushions; emergency trolley approach; general care with the fixation of the invasive devices and their permeability; eyeball protection; assessment of the patient's hemodynamic stability and the level of adequate analgesia and sedation(12).

The second step describes the role of each professional during the patient's prone maneuver. It emphasizes the importance of the medical professional or nurse, being positioned at the head of the bed to coordinate the rotation and attend to possible adverse events, being accidental extubation, displacement of the orotracheal tube (OTT), selective intubation and obstruction of the TOT, are the events most described in the literature. That despite being considered rare adverse events, they present a great risk to the patient's life and are thus a consequence that can interrupt the execution of the technique (3,12).

Priority should be given to the physician's presence at the patient's bedside position, in case of accidental extubation the professional will be closer to perform the new intubation (3). It is recommended that the nurse and the physiotherapist remain beside the patient's torso, being their attribution, consecutively, the care with the permeability of the invasive devices and that they are not pulled during the procedure and the adequacy of the mechanical ventilation parameters. It is up to the technicians to position themselves at the side, next to the patient's legs (3.12).

The third stage of the prone position consists of post-maneuver care that reduces the risk of developing complications associated with the prone position. For the interdisciplinary guideline, nurses are responsible for organizing care for people with ARDS in the prone position, as well as evaluating any changes in patient stability and preventing complications(5). It is up to nurses to prescribe care for prevent pressure injuries, such as alternating upper and lower limbs and face every two hours, recording gastric stasis and keeping the patient in reverse trendelenburg to avoid face swelling. Relieve pressure zones with the use of cushions, monitor skin integrity, ensure eve care such as hygiene, lubrication and protection, correct positioning of extensions and device fixations(3,12).

In the third stage, the team must assess the evolution of the patient's clinical condition for possible complications that prevent him from remaining in the position for the stipulated time. It is the physiotherapist's responsibility to adjust the ventilatory parameters and monitor the respiratory pattern, perform the alveolar recruitment maneuver and calculate ideal PEEP if clinically indicated (3).

The fourth step is the return of the patient to the supine position when he reaches the goal, FiO2/PaO2 reaction greater than 150 or because he presents hemodynamic instability in the prone position (13), this last step is a multidisciplinary assignment.

After the SOP is constructed and validated, it is necessary to present it to health service professionals, in addition to offering training to improve the technique. SOPs are effective instruments in the process of changing care practice, promoting improvements in

the results and performance of professionals, this is the starting point of all training or improvement (7).

It is worth highlighting the need for continuous reassessment with regard to fundamental elaboration actions so that the protocols in clinical nursing practice are widely used, as they promote high quality of care provided by health professionals who use the protocols, since the change in the way of performing the interventions is perceived, consequently with the deepening of knowledge (11).

CONCLUSION

It is concluded that the SOP for positioning the prone technique in the ICU constructed by this study has content and appearance validity, consisting of 76 items divided into four stages, before prone, prone maneuver, patient in prone position and return the dorsal position. It was approved by the 24 judges, those professionals from the multidisciplinary team of the ICU in guestion who use the technique daily, in the first round with CVI >80% for all items.

It is worth mentioning that POP was developed to be performed in adults. Clinical validation in care practice is recommended; aims to offer greater reliability and safety to patients and professionals, after content validation.

It is noteworthy that prone is a low-cost technique because it does not require specific equipment for its execution, it is easy to perform when professionals are trained and with beneficial results for the patient when well indicated, with this we reinforce the need to develop a SOP and knowledge of the multidisciplinary team to act appropriately. The use of prone SOP facilitates the correct execution of the procedure, improving the conduct of the multidisciplinary team and reducing intercurrences.



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