Revista Brasileira de Enfermagem
REBEn

RESEARCH

Validation of a care protocol for the septic patient in the Intensive Care Unit

Validação de protocolo assistencial ao paciente séptico na Unidade de Terapia Intensiva

Validación de protocolo asistencial al paciente séptico en la Unidad de Terapia Intensiva

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How to cite this article:
Pedrosa KKA, Oliveira SA, Machado RC. Validation of a care protocol for the septic patient in the Intensive Care Unit. Rev Bras Enferm [Internet]. 2018;71(3):1106-14. DOI: http://dx.doi.org/10.1590/0034-7167-2017-0312

Submission: 05-09-2017 **Approval:** 06-19-2017

ABSTRACT

Objective: to elaborate and validate a protocol for the care of the nurse to the septic patient in Intensive Care Units (ICUs). **Method**: instrument validation study. Two steps were followed: instrument development and content validation according to the Delphi technique. **Results:** the validation of contents related to the nurse's assistance to the septic patient in intensive care was initially composed of eighteen items analyzed by the evaluators/judges. From this, through the Content Validity Index (CVI), thirteen items with strong evidence of validation were identified, CVI = 0.79. Then the instrument was refined, being then composed of fifteen items, which in the second phase Delphi had a percentage of agreement above 84% for the variables pertinent to the protocol. **Conclusion:** the method was effective to validate the contents of a protocol for the nurse's assistance to the septic patient in the ICU. **Descriptors:** Sepsis; Nursing; Validation Studies; Clinical Protocols; Intensive Care Unit.

RESUMO

Objetivo: elaborar e validar um protocolo para assistência do enfermeiro ao paciente séptico em Unidades de Terapia Intensiva (UTI). **Método**: estudo de validação metodológica de instrumento. Foram seguidas duas etapas: elaboração do instrumento e validação de conteúdo segundo a técnica Delphi. **Resultados:** a validação de conteúdo referente à assistência do enfermeiro ao paciente séptico em terapia intensiva inicialmente foi composto por dezoito itens analisados pelos avaliadores/juízes. Deste, por meio do Índice de Validade de Conteúdo (IVC), identificou-se treze itens com forte evidência de validação, IVC = 0,79. A seguir o instrumento foi refinado, sendo então composto por quinze itens, que na 2ª fase Delphi possuiu percentual de concordância acima de 84% para as variáveis pertinentes ao protocolo. **Conclusão:** o método foi eficaz para validar o conteúdo de um protocolo para assistência do enfermeiro ao paciente séptico na UTI.
Descritores: Sepse; Enfermagem; Estudos de Validação; Protocolos Clínicos; Unidade de Terapia Intensiva.

RESUMEN

Objetivo: elaborar y validar un protocolo para asistencia del enfermero al paciente séptico en Unidades de Terapia Intensiva (UTI). **Método:** estudio de la validación metodológica de instrumento. Dos etapas fueron seguidas: la elaboración del instrumento y la validación del contenido de acuerdo con la técnica Delphi. **Resultados:** la validación del contenido referente a la asistencia del enfermero al paciente séptico en terapia intensiva fue inicialmente compuesta por dieciocho elementos analizados por los evaluadores/jueces. De este, a través del Índice de Validez de Contenido (IVC), se identificaron trece elementos con fuerte evidencia de validación, IVC = 0,79. A continuación, el instrumento fue refinado, siendo pues compuesto por quince elementos, que en la segunda fase Delphi presentó porcentual de concordancia superior al 84% para las variables pertinentes al protocolo. **Conclusión:** el método fue eficaz para validar el contenido de un protocolo para la asistencia del enfermero al paciente séptico en la UTI.
Descriptores: Sepsis; Enfermería; Estudios de Validación; Protocolos Clínicos; Unidad de Terapia Intensiva.

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INTRODUCTION

Sepsis is an important socioeconomic problem for world public health, being the main cause of death in Intensive Care Units (ICUs). It affects one year, millions of people, with a high mortality rate, matching the cases of acute myocardial infarction, stroke and polytrauma[1-3].

Sepsis is defined as a potentially fatal organic dysfunction resulting from a deregulated immune response to an infection progressing to the septic shock clinic when there are circulatory, cellular and metabolic abnormalities capable of substantially increasing mortality[3-4].

Sepsis and septic shock represent the temporal evolution of the same syndrome with different severity spectra associated with increasing mortality rates[1,3]. There has been a marked increase in the risk of death in patients diagnosed after 48 hours of organ dysfunction[4].

The international guidelines of the Surviving Sepsis Campaign state that the adequate identification of suggestive signs and symptoms significantly reduces the detection time of patients at risk of sepsis, favoring early treatment with better results[1]. To this end, the trained and dynamic health team is paramount, emphasizing that nursing, by attending the patient in an integral way to the bedside in the 24 hours, occupies a prominent role in the identification of signs of sepsis and risk factors for its development[5], and the quality of care resulting from clinical practice based on evidence[6].

In this perspective, the construction of a practical and systematized instrument, based on international guidelines and the analysis of concordance between evaluators, is expected to contribute to the nurses' role in the early diagnosis and treatment of sepsis, minimizing associated mortality. Therefore, the study aimed to elaborate and validate a protocol for the care of the nurse to the septic patient in Intensive Care Units.

OBJECTIVE

To elaborate and validate a protocol for the care of the nurse to the septic patient in Intensive Care Units.

METHOD

Ethical aspects

The study respected the formal requirements contained in the national and international standards regulating research involving human beings, and was approved by the Research Ethics Committee of the Universidade Federal do Rio Grande do Norte. All the participants signed the Free and Clarified Consent Term (FCCT).

Design, place of the study and period

Instrument validation study. The methodological trajectory followed two stages: elaboration of the instrument and validation of content of the protocol according to the Delphi technique.

We searched the literature through scientific databases: LILACS; SCIELO; PUBMED, in the period from July to November 2014, in studies of the last five years to support the variables of the instrument of data collection.

For the validation of the content of the instrument, the evaluators/judges for advanced search on the Lattes Platform were selected from the website of the National Council for Scientific and Technological Development (CNPq). The strategy for the selection of evaluators/judges in April 2015 was based on the defining characteristics assigned. Eighty professionals were contacted by electronic mail, e-mail, through a formal letter regarding the objectives, purpose and development of the study, in addition to requesting the consent, through the signature of the FCCT.

Sample, inclusion and exclusion criteria

The criteria for inclusion of the evaluators/judges were: to be a nurse with a master degree and/or doctor in high complexity and/or instrument/protocol validation studies and to have at least one year of experience in an Intensive Care Unit. The sample universe was dependent on the intentionality of the subjects who fulfilled the inclusion criteria.

Exclusion criteria were: not participating in the entire data collection process.

Study protocol

It was proposed a specific data collection instrument composed of two parts, the first referring to the professional characterization of the subjects and the second with items that make up the nurse's assistance to the septic patient.

For the elaboration of the care protocol, the scientific literature[3,6-10] and the guidelines of the Surviving Sepsis Campaign[1] were searched using the following descriptors: Sepsis; Nursing; Intensive Care Unit; Validation Studies; Clinical Protocols, initially creating a protocol consisting of three main topics with 18 items: Topic 1 - Screening for sepsis and recognition of clinical manifestations (item 1); Topic 2 - Initial resuscitation package (control of the first six hours) (items 2-12); Topic 3 - Support treatment (items 13-18).

The validation of the content of the protocol was done by the Delphi technique, which consists of collecting data, tabulating and evaluating a particular topic through the judgment of experts in the subject. This criterion of validation is based on the convergent opinion of the evaluators and emphasizes the need for consensus among the group of participants[11].

In the first Delphi phase, from May to July 2015, forty-nine evaluators accepted to participate in the research; however, the convenience sample consisted of thirty-four evaluators who sent the opinion within the established period of thirty days, after receipt of the instrument.

The experts evaluated the instrument using the Likert scale, with categories in four levels of importance, with the selection of a single response for each instrument variable: Completely Adequate (4); Suitable (3); Partially adequate (2); Inadequate (1). The literature emphasizes that this scale facilitates the evaluation by providing a numerical score with different degrees of agreement regarding the affirmation and reaction of the subject[12].

For the statistical treatment in this phase, the following categories were considered: Completely Adequate (CA) and

Adequate (A) that obtained judgments approved in a favorable consensus of 80%, this concordance index being based on other validation studies[11-13]. Also in this step, a space for suggestions and considerations was made available, in an observation column, for each item of the instrument.

The analysis of the first stage led to a reformulation and refinement of the content of the initial instrument, which now consists of fifteen items. In the second Delphi phase, in August 2015, the reformulated instrument was sent to the same experts, who, upon receipt, had a 15-day return period; however, only twenty-six experts returned the protocol evaluated. The purpose of this stage was to analyze the representativeness, clarity and comprehensiveness of each item, evaluated in a dichotomous way, with YES or NO answers. At this stage, the experts were able to again make suggestions and observations relevant to the improvement of the instrument.

At the end of the validation, the protocol was composed of fifteen items related to the nurse's assistance to the septic patient; being excluded three items for not being considered relevant to the theme.

Results analysis and statistics

The numerical data obtained in the second stage were compiled with the aid of the Microsoft Excel® program and the statistical analysis made through the statistical program SPSS, version 20.0 for Windows. The descriptive analysis (frequency, mean, median and standard deviation) and inferential analysis were performed using Pearson's Chi-Square test (2X), using a value of 0.05 with a 95% confidence interval.

The agreement of the experts regarding the representativeness of the items in relation to the content was measured using the Content Validity Index (CVI), calculated by the number of evaluators agreeing with the item by the total number of evaluators. Regarding the sum of all "yes" answers and calculation of the agreement percentage, a value of 80% was adopted for the variables considered pertinent to the ICU septic patient care protocol.

RESULTS

In the first stage of Delphi, the sample consisted of thirty-four nurses, with a mean age of 40.4 (± 9.5) years, mostly female (91%), with a mean training time of 17,8 (± 9.60) years and coming from São Paulo (32%), followed by Rio Grande do Norte and Rio de Janeiro, both with 15%; Minas Gerais (12%) and the other states of the Federation (26%).

As for the degree, the majority were doctors (53%), academic masters (44%); or ICU specialists (3%). Of these, 79% worked in teaching, research and/or extension in the area of high complexity, and 100% had experience in ICUs, with an average time of 8.2 (± 6.2) years. There were differences of proportions for the variables: doctoral thesis on instrument/protocol validation studies (p = 0.006), master with dissertation on instrument/protocol validation studies (p = 0.002) and clinical practice of at least one year in ICU (p = 0.001).

Regarding the variables related to the study in the first stage of Delphi, thirty-four experts evaluated the instrument composed of eighteen items (Table 1).

The results show the Content Validity Index (CVI) extremely satisfactory for thirteen items, with a total CVI of 0.79.

In Delphi's 2nd stage, of the total number of experts, twenty-six returned with the analysis of the reformulated instrument, composed in that phase by fifteen items. Table 2 demonstrates the issues with levels of agreement above 84%, excellent agreement; reaching a total percentage of 95%.

Table 1 – Items of the nurse's assistance protocol to the septic patient in ICUs validated by the evaluators/judges in the first phase of Delphi, Natal, Rio Grande do Norte State, Brazil, 2015

Variable	Yes		No		Total		CVI
	n	%	n	%	n	%	
1. Identifying sepsis	26	76.5	8	23.5	34	100.0	0.76
2. Lactate	28	82.4	6	17.6	34	100.0	0.82
3. Cultures	28	82.4	6	17.6	34	100.0	0.82
4. Venous access	30	88.2	4	11.8	34	100.0	0.88
5. Antibiotic therapy	24	70.7	10	29.4	34	100.0	0.70
6. Volume replacement	26	76.5	8	23.5	34	100.0	0.76
7. Vasopressors	29	85.3	5	14.7	34	100.0	0.85
8. Hemodynamic evaluation	30	88.2	4	11.8	34	100.0	0.88
9. Lactate monitoring	28	82.4	6	17.6	34	100.0	0.82
10. Blood pressure	27	79.4	7	20.6	34	100.0	0.79
11. Focus/Source Control	28	82.4	6	17.6	34	100.0	0.80
12. Inotropic TTT	27	79.4	7	20.6	34	100.0	0.79
13. Ventilation	30	88.2	4	11.8	34	100.0	0.88
14. Hemotherapy	28	82.4	6	17.6	34	100.0	0.82
15. Glycemic control	24	70.7	10	29.4	34	100.0	0.70
16. Nutrition	25	73.5	9	26.5	34	100.0	0.73
17. Prophylaxis DVT	25	73.5	9	26.5	34	100.0	0.73
18. Prophylaxis stress ulcer	25	73.5	9	26.5	34	100.0	0.73

Note: Likert Scale: Completely Adequate or Adequate = Yes, Partially Adequate or Inadequate = No; CVI = Content Validity Index; ATB = Antibiotic therapy; TTT = Treatment; DVT = deep venous thrombosis.

Table 2 – Percentage of agreement of the items of the instrument in the second phase Delphi, based on the analysis of the evaluators, Natal, Rio Grande do Norte State, Brazil, 2015

Variable	Yes		No		Total	
	n	%	n	%	n	%
1. Identifying sepsis	26	100.0	0	0	26	100.0
2. Lactate	24	92.0	2	8	26	100.0
3. Cultures	26	100.0	0	0	26	100.0
4. Venous access	25	96.0	1	4	26	100.0
5. Antibiotic therapy	21	84.0	5	16.0	26	100.0
6. Volume replacement	25	96.0	1	4.0	26	100.0
7. Hemodynamic evaluation	25	96.0	1	4.0	26	100.0
8. Vasopressors	25	96.0	1	4.0	26	100.0
9. Inotropic treatment	25	96.0	1	4.0	26	100.0
10. Blood pressure	24	92.0	2	8.0	26	100.0
11. Focus/Source Control	25	96.0	1	4.0	26	100.0
12. Hemotherapy	25	96.0	1	4.0	26	100.0
13. Ventilation	24	92.0	2	8.0	26	100.0
14. Glycemic control	24	92.0	2	8.0	26	100.0
15. Nutrition	25	96.0	1	4.0	26	100.0

Chart 1 – Protocol for the care of the nurse to the septic patient, Natal, Rio Grande do Norte State, Brazil, 2015

ITEMS	DESCRIPTION	JUSTIFICATION
1) SEPSIS TREATMENT AND RECOGNITION OF CLINICAL MANIFESTATIONS		
Identifying sepsis	1.1.1 To perform routine screening on admission and in all patients with acute, potentially infected, acute diseases. 1.1.2 To know and identify diagnostic criteria of the systemic inflammatory response syndrome (SIRS), sepsis and septic shock: **SIRS:** Presence of two of the following: • central temperature (T) > 38.3º C or < 36ºC; • heart rate (HR) > 90 bpm; • respiratory rate (RR) > 20 rpm or partial pressure of carbon dioxide (PaCO2) < 32 mmHg ; • total leukocytes > 12,000/mm or < 4,000/mm³ or presence >10% of young forms (deviation to the left); **Sepsis: SIRS + organic dysfunction:** Main organic dysfunctions: • systolic blood pressure (SBP) < 90 mmHg or mean arterial pressure (PAM) < 65 mmHg ou drop in blood pressure (BP) > 40 mmHg ; • oliguria (≤0.5mL/kg/h) or elevated creatinine (> 2mg/dL); • partial oxygen pressure/inspiratory fraction ratio of oxygen < 300 (PaO2/FiO2 < 300), need for oxygen (O2) to maintain peripheral oxygen saturation (SpO2) > 90%; • platelet counts < 100,000/mm³ or a 50% reduction in the number of platelets in relation to the highest value recorded in last 3 days; • unexplained metabolic acidosis: base deficit ≤ 5.0 mEq/L and lactate > than normal value; • lowering of consciousness level, agitation, delirium; • significant increase in bilirubin (> 2x the reference value) **Septic Shock:** Hypotension refractory to volume replacement Note: SIRS criteria are no longer required for the diagnosis of sepsis, but they to increase sensitivity in detecting potentially serious cases[3,15]. Source: Instituto Latino Americano Sepse (ILAS), 2016.	To favor early diagnosis and treatment[1,14]. To improve hospital performance in sepsis[4];
2) INITIAL MEASURES PACKAGE FOR SEPSE (FIRST SIX HOURS CONTROL)		
Lactate	2.1.1 To collect blood samples for lactate dosing in the first hour of admission to the ICU in order to identify hyperlactatemia. 2.1.2 Perform sequential monitoring of lactate in patients with initial hyperlactatemia, measuring their values every two to three hours until the reduction to normal serum levels (lactate bleaching) (medical conduct).	-To favor the diagnosis of organic dysfunction[1,3]; -To evaluate tissue hypoperfusion and adequacy of initial resuscitation operations[1,14];
Cultures	2.2.1 To collect two blood cultures at different sites before the start of the antibiotic therapy, preferably one in the peripheral vein and another in a central vascular access device, if present, and if it has been recently inserted (< 48 hours), according to the protocol of the unit and/or prescription. 2.2.2 To collect cultures from all sites relevant to the suspected infection focus (uroculture, abscess secretions, catheter tips, tracheal secretions, among others) ideally before antimicrobial treatment begins. 2.2.3 Perform the collection of laboratory tests: arterial blood gas; hemoglobin, coagulogram, creatinine, bilirubin, and C-reactive protein (CRP).	-To identify micro-organism that causes infection for correct antibiotic therapy[1,14]; -To evaluate organic dysfunction[1,14].
Venous Access	2.3.1 To puncture large-caliber peripheral venous access (PVA). 2.3.2 To assist in the passage of a central venous catheter (CVC), when there is indication of the use of vasopressors or the difficulty of peripheral access. Give preferences for double lumen catheter. 2.3.3 To identify and note date and time of CVC insertion. 2.3.4 To perform aseptic dressings on the CVC.	-Safe administration of prescribed medications, fluids, and blood products; -To prevent primary infections bloodstream infections (BSI) associated with the catheter[15].
ATB	2.4.1 To administer broad-spectrum antibiotics intravenously, ideally within one hour of diagnosis. 2.4.2 To evaluate the possibility of antimicrobial descaling based on the microbiological data (medical team and hospital infection commission).	-To institute early antibiotic therapy, with adequate spectrum for the presented infection[1,14].
Volume replacement	2.5.1 To administer and supervise crystalloid infusion (30 ml/kg) as the initial choice fluid as prescribed. 2.5.2 To evaluate examinations and report possible changes.	-To maintain hemodynamic stabilization to prevent tissue hypoperfusion[1,14].

To be continued

Chart 1

ITEMS	DESCRIPTION	JUSTIFICATION
2) INITIAL MEASURES PACKAGE FOR SEPSE (FIRST SIX HOURS CONTROL)		
Hemodynamic evaluation	2.6.1 To perform complete hemodynamic evaluations at the bedside during the first six hours, discussing changes with the multidisciplinary team, goals: MAP ≥ 65 mmHg; control of water balance to obtain urinary volume ≥ 0.5 ml/kg/h; to identify abnormalities in HR, RR and distal perfusion. BP, HR,PVA	-To identify clinical complications[1,4,14]; -To avoid tissue hypoperfusion[1,4,14]; -To evaluate the adequacy of the initial volume replacement[1,4,14].
Vasopressors	2.7.1 To administer adjunctive therapy with vasopressors, according to medical prescription, for stabilization of MAP ≥ 65mmHg if hypotension does not respond to initial resuscitation with fluids. 2.7.2 Attention to care in the administration of vasopressors: strict control of BP, HR, urine output and peripheral perfusion; presence of phlebitis in the administration of vasoactive drugs by PVA; correct identification of infusion vasopressor solutions; administration of vasoactive drugs in distal lumen exclusive to CVC; side effects (decreased cardiac output, sweating, hypertensive peak, peripheral hypoperfusion).	-To maintain hemodynamic stabilization[1,14]; -To attempt for signs of clinical worsening[1,14]; -To identify adverse drug reactions[15]; -To certify the safety in the administration of medications[15];
Inotropic TTT	2.8.1 To administer dobutamine with a dose of 2-20 μg/kg/min, according to medical prescription, usually associated with the vasopressor. 2.8.2 To monitor the dobutamine infusion, considering: arrhythmias, excessive oscillations of BP, hypothermia, headache, nausea, anxiety, tremors and hypokalemia.	-To Improve myocardial dysfunction[1,14]; -To attempt for clinical signs of complication; -To identify adverse drug reactions[15].
BP monitoring	2.9.1 To provide arterial access for continuous monitoring of pressure. Maintain MAP > 65 mmHg (between 65 and 80 mmHg). 2.9.2 Caring for arterial catheter maintenance; 2.9.3 Constantly evaluate the punctured member for perfusion, T, pulse width and staining.	- Monitorar sinais indicativos de instabilidade hemodinâmica[14]; -Identificar complicações relacionadas ao dispositivo arterial[16]; -Manter cateter permeável[16].
Focus/Source Control	2.10.1 To identify and control infectious disease: abscess drainage, necrotic tissue debridement, removal of potentially infected invasive device (delayed bladder probe, CVC), early weaning from mechanical ventilation, with definitive control of the source of microbial contamination within the hours after diagnosis. 2.10.2 To evaluate and report possible outbreaks of infection;	-To identify infectious focus to institute appropriate treatment[1,14]; -To stop invading the patient to minimize the risk of reinfections[16].
3) SUPPORT TREATMENT		
Hemotherapy	3.1.1 To provide and administer the blood component, respecting its maximum time of infusion, according to medical prescription. 3.1.2 To verify and record vital signs (VS): T, HR, BP and RR according to service protocol. 3.1.3 To check the patient's identification data on the bag identification label with the medical record and the medical prescription; 3.1.4 To use PVA or lumen of the exclusive CVC during transfusion; 3.1.5 To identify and report adverse reactions during and up to 24 hours after transfusion; * RESOLUTION COFEN-306/2006; PORTAL Nº 158/2016.	-To maintain hemodynamic stabilization[14]; -To collect safety requirements in the administration of the blood component[17-18]; -To identify transfusion reactions and institute treatment[17-18].
Ventilatory support	3.2.1 To observe breathing parameters: SpO2, PaCO2, PaO2 and pH; skin color - cyanosis, capillary perfusion and RR. 3.2.2 To indicate mechanical ventilation (MV) for acute respiratory distress syndrome (ARDS) induced by sepsis (multidisciplinary team); 3.2.3 To minimize VM risks: hand hygiene; monitor ventilatory parameters; care for the ventilation circuit (presence of dirt, leaks, periodicity of the exchange); monitor cuff pressure of the orotracheal tube every 12 hours, maintaining values of 20 to 30 mmHg (physiotherapist); apply good practices in upper airway and upper airway aspiration; keep the head of the bed between 30 and 45; perform oral hygiene with 0.12% chlorhexidine, 3x daily.	-To minimize acute lung injury[1,14]; - To avoid hypoxia[1,14]; -To prevent ventilator-associated pneumonia (VAP) [1,14,16].
Glycemic control	3.3.1 To monitor glycemic levels every 1 to 2 hours and after glycemic stabilization every 4 hours. Initiate insulin therapy after two consecutive levels of blood sugar greater than 180 mg/dL. 3.3.2 To follow protocol for hyperglycemia/hypoglycemia of the institution. 3.3.3 To observe signs and symptoms of dehydration, hyperglycemia, hypoglycemia, hydroelectrolytic imbalance, among others.	-To maintain blood sugar ≤ 180 mg/dL glucose to prevent hypoglycaemia and large oscillations[1].

To be continued

Chart 1 (concluded)

ITEMS	DESCRIPTION	JUSTIFICATION
3) SUPPORT TREATMENT		
Nutrition	3.4.1 To administer oral feeding, according to medical indication and tolerated by the patient. 3.4.2 To avoid absolute fasting. 3.4.3 To insert nasogastric (NG) or nasoenteral (NE) probe, for feeding in severe patients with digestive tolerance, by medical prescription. 3.4.4 To care in enteral diet administration: confirm gastric or post-pyloric positioning of the probe; administering the diet continuously or intermittently - 3/3h; keep head of bed elevated; evaluate presence of abdominal distension, vomiting and characteristic of bowel movements; blood glucose values and gastric residue, if prescribed. 3.4.5 To administer parenteral nutrition prescribed by CVC.	-To prevent malnutrition[19]; -To prevent complications due to absolute fasting[19-20]; -To avoid bacterial translocation[20].

Note: SIRS = Systemic inflammatory response syndrome; T = central temperature; HR = Heart rate; RR = Respiratory rate; PaCO2 = partial pressure of carbon dioxide; MAP = Mean arterial pressure; PaO2/FiO2 = Oxygen partial pressure/oxygen inspiratory fraction ratio; SpO2 = Peripheral oxygen saturation; ILAS = Instituto Latino Americano Sepse; CRP = C-reactive protein; PVA = Peripheral venous access; CVC = Central venous catheter; BSI = Primary bloodstream infections; VS = Vital signs.

DISCUSSION

The theoretical content that structures this instrument is based on the best clinical evidence[1,3,14-21], being readapted, after validation of its content by specialists, in which the mixture of visions, cultures and scientific knowledge, makes the product[14]. The use of protocols for specific demands is of paramount importance to the health care organization, for establishing effective procedures and conducts the optimization of the work process, presiding over the care practice with the minimum of treatment variations[21].

Sepsis patients occupy about 10% of the beds of Intensive Care Units, representing the main cause of deaths in non-cardiologic ICUs[6]. The new guidelines of the Surviving Sepsis Campaign recommend the routine use of sepsis screening devices[1], emphasizing that the construction and validation of specific protocols with adequate methodology can guide nursing care for this clientele

In the first phase of Delphi, five items presented CVI lower than 0.75. The analysis of the data and suggestions of the experts generated adaptations of three of them: antibiotic therapy, glycemic control and nutrition were reformulated in text and theoretical basis[1,14,19-20], being kept in the protocol because they are relevant to the nurse's assistance to the patient septic. Two items assessed as unfounded were excluded: prophylaxis for deep vein thrombosis and prophylaxis ulcer stress. Two items were regrouped: lactate monitoring with lactate and mechanical ventilation with ventilatory support. In addition, the other items obtained a high index of agreement among the evaluators.

Screening for sepsis and recognition of clinical manifestations is paramount to diagnosis and early therapy[1,3]. According to the new international guidelines, sepsis is defined as the presence of potentially fatal organic dysfunction due to deregulated immune response to infection[1,3,15], with SIRS no longer necessary for its diagnosis and the term sepsis, severe extinct[3]. However, in spite of the advantages of the consensus, the criteria of organic dysfunction were modified, based on mortality prediction score, SOFA-Sequential Organ Failure Assessment, which restricted the diagnosis of sepsis to severe cases, harming countries with limited resources that aim increase their sensitivity[14,22]. Thus, this protocol maintains the criteria of organic dysfunction advocated by ILAS, which obtained a high degree of agreement among the evaluators.

As for the initial sepsis package, this one seeks the reversal of tissue hypoperfusion[1,14], with the temporal aspect and the order of therapeutic interventions vital to patient management in the first 3h and 6h of diagnosis[14]. Among its constituent items, lactate is a biomarker of organic dysfunction, hyperlactemia due to secondary anaerobic metabolism due to poor tissue perfusion in sepsis, its evaluation must be performed in suspect cases, as well as in the first hours after resuscitation in which the decrease of lactate by 10%, or values lower than 2 mmol/L, are related to the better prognosis of septic patients[14,23-24].

The aim of this study was to identify the causative agent of sepsis for antimicrobial de-escalation. Among them, blood culture is highly specific in the detection of bloodstream infection (BSI), whose sources are varied and mainly due to intravascular devices (19%), genitourinary (17%) and respiratory tract (12%)[14,25].

It is recommended that the collection of blood cultures, as well as materials of foci suspected of infection (cerebrospinal fluid, urine, feces, secretions, abscesses and others) should ideally be done prior to the initiation of antibiotic therapy in patients with a clinic suggestive of infection[24], In general, two to three sequential samples (two vials per puncture/sample) are collected in a short time, allowing the isolation of the bacterial or fungal agent in more than 95% of the events[14,26].

The laboratory analysis complements the diagnosis of organic dysfunction, indicating the application of the SOFA score in the ICU[3]. In addition, it provides information pertaining to treatment adequacy. Lactic acidosis may be due to tissue hypoperfusion, in the same way that hyperchloremic acidosis may be secondary to excess replacement of chloride-rich fluids[14]. Hypoxemia, hypercapnia or hypocapnia assist the interpretation of the pathophysiology of the ventilatory or perfusional disorder[14]. As for the hematological analysis, it is commonly found in sepsis, leukocytosis or leucopenia, with frank thrombocytopenia associated with the worst prognosis[14]. The change in coagulogram may culminate with the installation of disseminated intravascular coagulation (DIC)[14]. Elevated levels of total and direct bilirubin ($>2X$ the reference value) are indicative of hepatocellular damage[3,14]. On the other hand, renal dysfunction is characterized by increased serum creatinine ($\geq 2mg/dl$) associated with oliguria ($\leq 0.5mL/kg/h$)[1,3,14].

The item antibiotic therapy was modified to focus on the care of the nurse in its administration. In sepsis, the administration of broad-spectrum antibiotics should be performed after collection of cultures at the 1st hour of diagnosis, as the delay in administration of antibiotic therapy increases the risk of death[1,14].

Volume replacement with crystalloids is indicated in the presence of hypotension or hyperlactatemia (lactate levels twice the reference value) in the first three hours of septic patient care, in order to restore adequate blood flow and tissue supply of oxygen, which may be maintained while there is hemodynamic improvement[1,14]. There is no evidence in the literature of the superiority of the synthetic or natural colloid on the crystalloid[14]. As for human albumin, it was excluded from the protocol, since even contributing to maintenance of blood volume without increasing interstitial edema, there are no recommendations for its routine use in cases of sepsis and trauma[27-28].

The purpose of hemodynamic evaluation, as well as continuous blood pressure monitoring, is to measure the efficacy of initial resuscitation maneuvers in the first 6 hours of treatment[14].

In sepsis, the use of vasopressors is reserved for cases of hypotension that is refractory to volume replacement[1,14]. The drug of first choice is noradrenaline, and the addition of vasopressin (up to 0.03U/min) or adrenaline to noradrenaline solution, aims to raise the mean arterial pressure. In addition, vasopressin is indicated for weaning from noradrenaline[1,14]. Dopamine is limited to selected patients, who have a low risk of tachyarrhythmias and relative or absolute bradycardia, and should be administered via a central catheter[1,14]. Inotropic treatment is used in myocardial dysfunction, the drug of choice being dobutamine[14]. Levosimendan and milrinone are options for increasing cardiac output in specific situations. However, due to the low quality of evidence and limited number of studies, the use of dobutamine remains[1].

Regarding the control of the focus/source in sepsis, it is sought to identify the sites that trigger the infection in order to institute specific control measures, implemented after successful initial resuscitation[1,14].

Regarding the importance of the treatment of support for sepsis, there was a favorable consensus among the experts on the items addressed in the protocol. In hemotherapy, nursing conducts and care in safe blood transfusion were emphasized in accordance with Resolution COFEN-306/2006[17] and Ordinance No. 158/2016[18]. Although there is no optimal level of hemoglobin for septic patients, hemoglobin concentration below 7 g/dL is indicated in the absence of myocardial ischemia, severe hypoxemia or acute hemorrhage[1,14]. The administration of fresh frozen plasma to these patients should not be performed to correct coagulopathies without active bleeding[1]. Prophylactic platelet transfusion is indicated in values below 10000/mm3 in the absence of bleeding or 20,000/mm3 in patients with a significant risk of bleeding[1].

The item mechanical ventilation was regrouped next to the ventilatory support, because not necessarily septic patients will make use of invasive mechanical ventilation. The identification of signs suggestive of respiratory worsening minimizes the occurrence of acute lung injury induced by sepsis, in which protective mechanical ventilation acts as a strategy of better prognosis[1]. It is recommended to ventilate the patient with a tidal volume of 6ml/kg of predicted weight, maintaining plateau pressure below 30 cm H2O with high PEEP. In patients with PaO2/FiO2 $<$150 ratio, the use of the prone position and the initiation of neuromuscular blockers for a period shorter than 48 hours[1] is indicated. In these cases, the performance of the multidisciplinary team should focus on patient monitoring, to prevent potential complications and to minimize the risks of ventilator-associated pneumonia (VAP), implementing, as soon as hemodynamic stability, the institution's weaning protocol[1,16].

Regarding glycemic control, septic patients' treatment goals are to maintain blood glucose levels below 180mg/dL, avoiding hypoglycemia and large glucose oscillations related to increased mortality[1,29]. The values of capillary blood sugar should be interpreted with caution, being not accurate as to the serum values, in this way; its dosage in arterial blood is recommended if the patient uses a catheter for this purpose. There are controversies in the literature on the efficacy of glycemic control in adults, however, many ICUs, surgical units and burn units bring positive feedback from this follow-up[29].

As for balanced nutrition, this favors lower rates of hypoglycemia, minimizes the deterioration of nutritional status and complications resulting from absolute fasting[19]. It should be instituted early in sepsis and septic shock, preferably enterally, which is more physiological and safe, preventing bacterial translocation[20]. Parenteral nutrition alone or in combination with enteral feeding should be avoided in the first seven days because it favors infections and does not reduce the mortality rate[1].

However, prophylaxis items for deep venous thrombosis (DVT) and prophylaxis for stress ulcer were excluded from the protocol after statistical treatment. According to the experts' considerations, these actions are not directly related to sepsis, and it is pertinent to keep only specific items in the protocol.

The use of protocols provides a scientific framework for critical patient care, favoring the autonomy of the multidisciplinary team and the updating of knowledge based on scientific evidence[13,19]. With the increased incidence of sepsis, there is a need to adopt efficient measures, both individually and collectively, so that the team is able to initiate treatment in an early, dynamic and effective way, minimizing the associated mortality. It should be noted that all items with strong evidence of validation in the nurse's protocol to the septic patient should subsequently be submitted to clinical validation studies to verify their effectiveness.

Study limitations

The limitations of the study were derived from the sample universe determined by the choice of participants via Platform Lattes. In addition to the refusal of some subjects to participate in the study, others did not return the instrument in the second phase, thus reducing the sample for convenience.

Contributions to the area of Nursing, health or public policy

Considering sepsis as a global public health problem, whose time is a determining factor for the worst prognosis, this study may favor the implantation of a standardized care protocol for septic patient care with consequent early interventions.

CONCLUSION

From the validation of content by evaluators/judges, a protocol was constructed with fifteen items referring to the nurse's assistance to the septic patient in the ICU, in order to guide health professionals to assist these patients in a timely, effective and with quality.

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