CONSTRUCTION AND VALIDATION OF FORM CONTENTS FOR SEPTIC PATIENTS
CONSTRUÇÃO E VALIDAÇÃO DE CONTEÚDO DE FORMULÁRIO PARA PACIENTES SÉPTICOS
CONSTRUCCIÓN Y VALIDACIÓN DE CONTENIDO DE FORMULARIO PARA PACIENTES SÉPTICOS

Natasha Varjão Volpáti¹, Patrícia Rezende do Prado², Luís Eduardo Maggi³

ABSTRACT

Objective: to construct an instrument for the collection of data from patients with sepsis of abdominal focus in Intensive Care Units (ICU). **Method:** this is a methodological study, construction and validation of content, carried out in three stages: integrative literature review; instrument construction and validation of instrument content. The results were presented in the form of figures. **Results:** the instrument was validated by 23 judges, of which 18 (78.3%) were nurses and five (21.7%) were physicians. It is pointed out that the instrument resulted in 84 variables divided into six domains. It is noted that, after the contributions, all the evaluators judged that the items are sufficient. **Conclusion:** it is concluded that the instrument constructed is valid, according to experts, for systematic data collection of septic patients with abdominal focus in Intensive Care Units. **Descriptors:** Validation Studies; Sepsis; Abdomen; Intensive Care Units; Data collection; Risk factors.

RESUMO

Objetivo: construir um instrumento para a coleta de dados de pacientes com sepse de foco abdominal em Unidades de Terapia Intensiva (UTI). **Método:** trata-se de um estudo metodológico, de construção e validação de conteúdo, realizado em três etapas: revisão integrativa da literatura; construção do instrumento e validação de conteúdo do instrumento. Apresentaram-se os resultados em forma de figuras. **Resultados:** validou-se o instrumento por 23 juízes, sendo 18 (78,3%) enfermeiros e cinco (21,7%) médicos. Aponta-se que o instrumento resultou em 84 variáveis divididas em seis domínios. Constata-se que, após as contribuições, todos os avaliadores julgaram que os itens são suficientes. **Conclusão:** conclui-se que o instrumento construído é válido, segundo os especialistas, para a coleta de dados de forma sistematizada dos pacientes sépticos de foco abdominal em Unidades de Terapia Intensiva. **Descritores:** Estudos de Validação; Sepse; Abdome; Unidades de Terapia Intensiva; Coleta de Dados; Fatores de Risco.

RESUMEN

Objetivo: construir un instrumento para la recolección de datos de pacientes con sepsis de foco abdominal en Unidades de Terapia Intensiva (UTI). **Método:** se trata de un estudio metodológico, de construcción y validación de contenido, realizado en tres etapas: revisión integrativa de la literatura; construcción del instrumento y validación de contenido del instrumento. Se presentaron los resultados en forma de figuras. **Resultados:** se validó el instrumento por 23 jueces, siendo 18 (78,3%) enfermeros y cinco (21,7%) médicos. Se señala que el instrumento resultó en 84 variables divididas en seis dominios. Se constata que, después de las contribuciones, todos los evaluadores juzgaron que los ítems son suficientes. **Conclusión:** se concluye que el instrumento construido es válido, según los especialistas, para la recolección de datos de forma sistematizada de los pacientes sépticos de foco abdominal en Unidades de Terapia Intensiva. **Descriptores:** Estudios de Validación; sepsis; abdomen; Unidades de Terapia Intensiva; Recolección de datos; Factores de Riesgo.

^{1,2,3} Federal University of Acre/UFAC. Rio Branco (AC), Brazil. ORCID : <https://orcid.org/0000-0003-0057-5325> E-mail: naty_volpati@hotmail.com
ORCID : <https://orcid.org/0000-0002-3563-6602> E-mail: patyrezendep Prado@gmail.com; ORCID : <https://orcid.org/0000-0003-3931-7921> E-mail: luis.maggi@gmail.com

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INTRODUCTION

It is known that sepsis is currently the main cause of death in Intensive Care Units (ICUs) and one of the main causes of late hospital mortality, overcoming acute myocardial infarction and cancer.¹

In a study carried out in Brazil, it was pointed out that there was a 50.5% increase in the incidence of sepsis hospitalizations in the Unified Health System (UHS), between 2006 and 2015, and in the same period, General sepsis lethality rate was 46.3%, and 64.5% of the registered cases were due to hospitalizations in ICUs.²

According to the Third International Consensus on Sepsis and Septic Shock Definitions, sepsis is defined as life-threatening organ dysfunction caused by a host response to dysregulated infection. One organ dysfunction can be identified as an acute change in the Sequential Organ Failure Assessment (qSOFA) index. It is stated that a total score ≥ 2 points, as a result of infection, will be characterized by altered mental status, systolic blood pressure ≤ 100 mmHg, or respiratory rate ≥ 22 per minute. It is added that patients with septic shock can be identified by means of a clinical construction of sepsis marked by the persistence of hypotension, which requires the use of vasopressors to maintain mean arterial pressure (MAP) ≥ 65 mmHg and the serum level of lactate > 2 mmol / L (18 mg / dL), despite adequate volume replacement.³

It is noted that timely and adequate control of infectious focus remains a vital component in the definitive management of sepsis and, in particular, is critical to successful outcome in complicated abdominal infection. It is emphasized that abdominal sepsis is a result of both intra-abdominal and retroperitoneal infections.⁴⁻⁵

In a retrospective cohort study with patients diagnosed with sepsis and septic shock at a ICU in Rio Branco, Acre, it was identified that septic patients with a focus of abdominal infection presented the highest risk of death (HR: 3.71; 95% CI: 1.31-10.49) and 100% of these died at the end of 24 days of hospitalization.⁶

In view of the problem, it is of paramount importance that health professionals are instrumented, aiming to collaborate, thus, in the care of the patient with sepsis of abdominal focus. In this sense, we can contribute to the use of a validated questionnaire to systematize care and guarantee the quality and safety of care. It is justified, therefore, the interest in constructing and validating a specific instrument that makes it possible to collect data in a systematized form of patients with sepsis with abdominal focus.

The purpose of this study was to construct and validate the contents of an instrument for the

collection of data directed to patients diagnosed with abdominal sepsis in Intensive Care Units.

OBJECTIVES

- To construct an instrument for the data collection of patients with abdominal focus sepsis in Intensive Care Units (ICUs).
- Validate the instrument for data collection of patients with abdominal focus sepsis in Intensive Care Units (ICUs).

METHOD

This is a methodological study, with a quantitative approach, for the construction and validation of the contents of an instrument for the collection of data from patients admitted to the ICU, with a diagnosis of sepsis with abdominal focus.

It should be noted that the validity of an instrument represents the degree to which it measures the content it proposes to measure. Various validity forms are listed based on their relevance, completeness and accuracy: appearance validity; content; criterion and construct.⁷

For content validity, a subjective assessment, based on the opinion of judges from the content area, is required to determine if the instrument explores all the dimensions and domains pertinent to the concept or construct under study.⁷

It is said that this research contemplated three stages. Firstly, an integrative review of the literature for the elaboration of the items of the instrument was carried out, by means of the collection of articles published in periodicals indexed in the LILACS (Latin American and Caribbean Literature in Health Sciences) databases and MEDLINE (International Literature in Health and Biomedical Sciences), through the following keywords and descriptors: sepsis; Intensive Care Units; abdomen; abdominal focus; risk factors; death; instrument; construction and validation. The following inclusion criteria were selected: articles with complete texts and available online, in the English and Portuguese languages, published in the last ten years.

Then the second phase of the research was carried out: the construction of the instrument. After the scientific basis, the main items that presented relevance in the literature were identified, beginning the creation of the first version of the instrument. 83 items were categorized in six domains, mostly with multiple choice questions: epidemiological profile (15); abdominal surgical procedure (12); clinical profile in the first hour of ICU admission (33); evolution of the patient (12) and packages for the treatment of sepsis in the first three and six hours (12).

Finally, the third step was accomplished: the validation of the content of the instrument. In this stage, the validation of the instrument's content was performed, which consists in judging the domains present in the instrument in order to determine if they are compatible with what one wishes to measure. It should be noted that, unlike in other validation formats, content validation is not based on scores or differences between people, but on the support of experts regarding the content of the items ⁽⁸⁾.

Content validation was obtained through a panel of 23 judges selected for convenience, with expertise in the subject, whose inclusion criteria were: being a doctor or a nurse; have a minimum degree of specialization in Intensive Care or General Surgery; have an experience of more than or equal to two years in an ICU and / or surgical center and have an interest in participating in the research.

A questionnaire was created for the validation of the instrument, which was structured with an explanatory text, clarifying the purpose of the research and the activity requested of the judges, and including the approval opinion of the ethics committee, the Free and Informed Consent Term (FICT) and communication between investigators and judges. It is verified that the evaluation round took place in person.

It should be noted that the form of the questionnaire accompanied the instrument with the following questions in each area of the sheet: "Do you consider that the data is complete?"; "Would you add something? Which one?"; "Would you exclude any data? Which one?" It is recorded that, at the end of the evaluation, each professional performed a general judgment by means of a score from zero (bad) to ten (great), stating whether he would consider the applicable

clinical practice for data collection and whether he would like to make some observation. After the selection of the judges and the application of the validation questionnaires, the data in Microsoft Excel 2010 were analyzed by means of the Statistical Package for Social Sciences (SPSS), version 20.0. It is emphasized that the percentage of acceptable agreement for the validation of each item was above 70%. Considerations and adjustments of the instrument should be considered for results below this value.

The formal requirements contained in the national and international norms regulating research involving human beings were respected, and the study was approved on November 24, 2015 by CAAE n.47577215.2.0000.5009 of the State Hospital of Acre Foundation (FUNDHACRE).

RESULTS

The instrument was validated by 18 (78.3%) nurses and five (21.7%) physicians, of whom five (21.7%) were male and 18 (78.3%) were female, 20 (87.0%) lived in the State of Acre, one (4.3%) in São Paulo and two (8.7%) in Minas Gerais. It is known that they all had specialization in Intensive Care and / or General Surgery, as well as a time of experience of more than two years.

Figure 1 shows the six domains of the instrument that resulted, initially, from the bibliographical survey, in two pages, with 83 items, mostly containing objective questions, a facilitating factor for data collection. It is noteworthy that, after the round with the judges, the instrument was finalized with 84 items.

Figure 1. Descriptive diagram of the stages of the proposed evaluation instrument. Rio Branco (AC), Brazil, 2018.

In the first domain, the "epidemiological profile" includes general information such as the patient's name, date of birth, age, hospital registration number, hospital admission sector, date of admission to the ICU, initial diagnosis, the classification of sepsis at ICU admission, as well as the origin of the patient (Figure 2).

It was verified that 21 professionals (91.3%) judged it with complete data, but when

questioned about the inclusion of another item, six (26.1%) suggested the index of body mass, specification of previous comorbidities, allergies and color, and no professional indicated the exclusion of any item. It should be noted that, following adjustments, the instrument was made available to the judges for appretiation.

Area I: Epidemiological profile (after analysis of the judges)		
Name:		Date of birth: ____/____/____
Age:	BMI:	Register number:
Color: (1) White (2) Brown (3) Black (4) Indigenous	Alergiess: () No () Yes: _____ Sex: (1) Female (2) Male	Date of hospital admission: ____/____/____ Date of ICU admission: ____/____/____
Admission location: (1) Clinical Emergency Room (2) Trauma Emergency Room	Initial diagnosis:	Previous Comorbidities:
Classification of sepsis at ICU admission: (1) Sepsis (2) Septic shock (3) Organic dysfunction	Origin in admission to the ICU: (1) Surgical center (2) Trauma Emergency Room (3) Clinical Emergency Room (4) Infirmary_____	

Figure 2. Epidemiological profile. Rio Branco (AC), Brazil, 2018.

* (Body Mass Index - BMI) (Intensive Care Unit - ICU)

As regards the "Abdominal Surgical Procedure" (figure 3), information on whether surgery is performed or not is shown. It was defined, if surgery has been performed, that should be informed if it was elective or emergency and classify it also informing the date of the indication and the procedure, the duration of the surgical procedure, if antibiotics were given as prophylaxis, and transfusion of blood components. It is also worth noting that the main finding

identified in the procedure, as well as the surgeon responsible.

It was recorded that the five physicians (100%) and 17 nurses (94.4%) evaluated that they had complete data and six specialists (26.1%) suggested they: vital signs before the surgical procedure; volume and specification of the blood component infused during the surgical procedure and if there are interurrences during the procedure.

Area II: Abdominal surgical procedure (after examination by the judges)	
Surgery: (1) Yes (2) No	VVSS before the procedure:
Date of surgery appointment: ____/____/____	Initial BP:_____mmHg
Date of surgery: ____/____/____	ABP:_____mmHg Axt:____°C
Classification of surgery: (1) Clean (2) Contaminated Potential (3) Contaminated (4) Infected	HR:_____ RR:_____
	Time of surgical accomplishment: _____minutEs
	Antibiotic prophylaxis: (1) Yes (2) No
Transfusion of blood components: (1) Yes: Specify: _____volume:_____	Name of antibiotic:
	25. Surgeon in charge:
	26. Main finding in surgery:
(2) No	27. Intercurrences during the procedure:

Figure 3. Surgical procedure. Rio Branco (AC), Brazil, 2018.* (Vital signs: VVSS); (Millimeters of mercury - mmHg); (Blood pressure - BP); (Mean arterial pressure - ABP); (Axillary Temperature - Axt); (Heart rate - HR); (Respiratory rate - RR).

In the "clinical profile: 1st hour of admission to the ICU" domain, items used to evaluate the SOFA score, such as vital signs, the Glasgow Coma Scale Score and Rass score for sedated patients, use of a catheter central venous infusion, amine infusion, acute renal failure associated with clinical findings, and laboratory tests involving markers of hematological, renal, hepatic, tissue hypoxia, and sodium and potassium electrolytes (Figure 4).

It was noted that 22 (95.7%) professionals considered that the domain had complete data, but a physician and a nurse would add the culture

and the location of the central venous access, which were not included because there is a low degree of agreement and if the patient would be under invasive mechanical ventilation. It should be emphasized that no evaluator suggested the exclusion of any item.

In the respiratory system, items related to the presence or absence of the mechanical ventilation support were included in the arterial blood gas analysis, in relation to oxygen arterial pressure and to the inspired fraction of oxygen (PaO2/Fio2).

Area III: Clinical profile: 1 hour of ICU admission (after judges' analysis)			
28. Initial blood pressure: _____mmHg	29. Average blood pressure: _____mmHg	30. Invasive mechanical ventilation: (1)Yes (2)No	31. Fio2:
32. RR:	33. HR:	34. Relation of PaO2/Fio2:	35. Arterial pH:
36. Temperature:	37. Glasgow:	38. Arterial HCO3:	39. Arterial CO2:
40. Rass:	41. Lactato:	42. TGO (): _____	43. TGP (): _____
44. Direct bilirubin:	45. Albumine:	46. Urea:	47. Creatinine:
48. Sodium:	49. Potassium:	50. Hemoglobin:	51. Hematocrit:
52. Platelets:	53. Sticks:	54. Leucocytes:	
55. Intra-abdominal pressure: _____mmHg		56. Central venous pressure: _____mmHg	
57. Use of Central Venous Access: (1) Yes (2) No		58. Acute Kidney Failure: (1) Yes (2) No	
59. Use of amines: (1) Noradrenaline (2) Dopamine (3) Dobutamine		60. Chronic Health Problems: (1) Cirrhosis-Biopsy (2) CCI degree IV (3) Severe COPD: Hypercapnia, O2 Dependent, Pulmonary hypertension (4) Chronic Dialysis (5) Immunocompromised	

Figure 4. Clinical profile: first hour of ICU admission. Rio Branco (AC), Brazil, 2018.

* (Glutamic-oxalacetic transaminase - GOT); (Glutamic-pyruvic transaminase - GPT); (Carbon dioxide - CO₂); (bicarbonate - HCO₃); (Congestive heart failure - CHF); (Chronic Obstructive Pulmonary Disease - COPD); (Partial oxygen arterial pressure - PaO₂); (Fraction of oxygen inspired FiO₂).

The "patient evolution" is described in the fourth domain of the instrument, which included items such as microorganisms, antibiotics used in the course of treatment, length of stay, number of surgeries and peritoneostomy, colostomy, and nutritional therapy (Figure 5).

When evaluating this domain, 17 (94.4%) nurses and four physicians (80.0%) judged the present information to be complete, three evaluators

Volpáti NV, Prado PR do, Maggi LE.

(13.0%) would add items such as the outcome of the patient, and all judged that it was not

Construction and validation of form contents... necessary to exclude any item.

Area IV: Evolution of the patient (after analyzing the judges)			
Lenght of stay: (1) up to 7 days (2) up to 14 days (3) >14 days		Antibiotics used (specify):	
Number of surgical interventions:	Peritoneostomy: (1) Yes (2) No	Colostomy: (1) Yes (2) No	Total parenteral nutrition: (1) Yes (2) No
Enteral diet: (1) Yes (2) No	How many days of tracheal oral tube:	Tracheostomy: (1) Yes (2) No	Microorganisms: (1) gram-positive (2) gram-negative
Identification site of the microorganism:		Outcome: (1) Discharge (2) Death	

Figure 5. Evolution of the patient. Rio Branco (AC), Brazil, 2018.

It is noted in the fifth and penultimate part that the treatment for sepsis needs to be performed within the first three hours after diagnosis. Such conduct is considered fundamental for a favorable clinical outcome to the patient, as evidenced in the literature (1). It is pointed out that in this area it should be recorded if blood culture, blood gas, lactate, blood count,

creatinine and bilirubin were collected, as well as to verify if broad-spectrum antibiotics were administered in the first hour, according to medical prescription, and volume replacement was performed aggressive to hypotension or lactate two times higher than the reference value (Figure 6).

Area V: Treatment for sepsis: Three hours (after analysis of the judges)			
Hemoculture: (1) Yes (2) No	74. Gasometry: (1) Yes (2) No	75. Lactate: (1) Yes (2) No	76. Blood count: (1) Yes (2) No
77. Creatinine: (1) Yes (2) No	78. Bilirrubine: (1) Yes (2) No	79. Administration of broad spectrum antibiotic AMP in the first hour: (1) Yes (2) No	80. Aggressive volume replacement in the first hours for patients with hypotension or lactate twice the reference value: (1) Yes (2) No
Area VI: Treatment for sepsis: Six hours (after examination of the judges)			
81. Use of vasopressors to maintain mean blood pressure above 65 mmHg: (1) Yes (2) No	82. Re-evaluation of blood volume and tissue perfusion: (1) Yes (2) No	83. Re-evaluation of lactate levels in patients with initial hyperlactatemia: (1) Yes (2) No	
84. The following forms of revaluation were considered: (1) Yes (2) No Measurement of CVP Pulse pressure variation Passive elevation of lower limbs Any other form of fluid responsiveness Measurement of O2cVS, Capillary filling time Intensity of livedo, Indirect signs (eg improvement of level of consciousness or presence of diuresis).			

Figure 6. Treatment for sepsis. Rio Branco (AC), Brazil, 2018.* (Central venous pressure - CVP); (Central venous oxygen saturation - O2Cvs); (According to Medical Prescription - AMP); (Millimeters of mercury - mmHg).

It is noted that the treatment of sepsis for the first six hours is present in the last item of the instrument, in which the reassessment of the patient is emphasized. It is suggested, in this item that lactate, central venous pressure, pulse pressure, improvement of the level of consciousness, the presence of diuresis, the need to use vasopressors to maintain mean blood pressure above 65 mmHg and others.

In the last two domains, the sepsis treatment packages are present in the first three and six hours according to the recommendations of the Surviving Sepsis campaign ⁽¹⁾. It should be noted that there was no increase in items.

It was found that, at the end of the content validation process, 17 (86.9%) of the 23 evaluators judged the plug to be very good and 87.0% reported that the instrument was applicable to clinical practice.

It was also observed that all the professionals expressed that the instrument favors the collection of information from patients with sepsis of abdominal focus and that the data are sufficient to identify the risk factors related to death. It was also noticed that all agreed that there is no repetition of data or questions on the different axis.

DISCUSSION

It is worth noting that the process of constructing and validating the instrument was reached, considering that the six domains were able to measure what was proposed. It is argued that, from the use of this instrument for the collection of data, it will be possible to identify and analyze the risk factors for the occurrence of death in these patients.

It is emphasized that the initial part of the collection instrument consists of the epidemiological profile. In one study, the age variable is a predictive factor for mortality in patients with complicated intra-abdominal infections.⁹

It should be noted that this instrument also has variables that make up the predicted outcome scoring system and the severity index for patients admitted to ICUs: the SOFA (Sequential Assessment of Organ Failure) and APACHE II (Physiology Evaluation Acute and Chronic Health).

It is understood that the SOFA evaluates six organic systems (respiratory, cardiovascular, renal, hepatic, central nervous and coagulation), in which each function is scored from zero (normal function) to four (more abnormal), giving a possible score of zero to 24, that is, the higher the score, the greater the probability of death.¹⁰ The association between SOFA and the risk for mortality in sepsis patients is shown in studies.¹¹

As for the APACHE II assessment classification system, it is known that it uses a score based on initial values of 12 physiological routine measures, age and previous health status to provide a general measure of disease severity, uses information available in the medical record and provides a predictive outcome for mortality in critically ill patients.¹² It is evaluated that APACHE II scores are significantly higher in non-survivors with abdominal focus sepsis, therefore, this variable is fundamental in the instrument.¹³

The evolution of sepsis to septic shock is associated with a higher mortality, so early identification and clinical management at the first moment in patients with sepsis are of paramount importance. It is recommended to administer antimicrobial therapy intravenously as soon as possible.^{9,14}

It is noted that patients with sepsis may present with inadequate tissue perfusion, which may, in turn, lead to overall tissue hypoxia, resulting in elevated levels of serum lactate; Therefore, volume expansion through the infusion of crystalloids and / or colloids should be initiated in order to maintain a mean arterial pressure ≥ 65 mmHg and a lactate > 2 mmol / L (18 mg/dL).^{4,15}

It is highlighted in the literature, regarding the domain "abdominal surgical procedure", the importance of adequate control of origin in

abdominal sepsis, acting directly on the source of infection through the removal and drainage of its products together with antibiotic therapy and adequate ventilatory and hemodynamic supports.⁹ Ineffective septic source control is associated with significantly elevated mortality rates.⁴

In situations where patients are severely destabilized by septic shock, there is a greater benefit with aggressive surgical treatment, rapid intervention, and successive follow-up surgeries to better control multiple organ dysfunction triggered by ongoing intra-abdominal infection.¹⁶

It is also clear from the surgical procedure that the open abdomen remains a viable option for the treatment of intra-abdominal sepsis. The benefits include the ease of subsequent exploration, control of abdominal contents, reduction of the risk of intra-abdominal hypertension and abdominal compartment syndrome, and facial preservation, ensuring adequate closure of the abdominal wall. It should be noted, however, that prolonged exposure of the abdominal viscera may result in additional complications, including infection, sepsis, and fistula formation.⁴

Another important factor that must be followed in relation to a critical patient with sepsis of abdominal focus is the hospitalization time, which is directly related to the patient's outcome: the longer the stay, the greater the risk of death, as well as the presence of resistant microorganisms.¹⁷⁻⁸

Finally, it is pointed out that the last axis of the instrument contemplates the recommendations of the Latin American Sepsis Institute (LASI) of the Surviving Sepsis Campaign, recommending that the treatment of patients diagnosed with sepsis should occur in the first three to six hours and be based on eight diagnostic and therapeutic interventions, guiding institutional policies to ensure quality and safe care.¹

It is evaluated that this study has limitations because it is a validation of an instrument elaborated for a specific pathology, however, it can serve as a parameter for future studies.

CONCLUSION

It is concluded that the instrument constructed is valid, according to the judges, to measure the six domains for monitoring and evaluation of the septic patient of abdominal focus in ICU. It is argued that this study will contribute to the expansion of the knowledge of the health care team, emphasizing that it will subsidize, in particular, the Nursing team in order to provide adequate care to the patient with sepsis of abdominal focus.

In this sense, it is argued that the instrument has the potential to contribute not only to the monitoring of mortality indicators due to

Volpáti NV, Prado PR do, Maggi LE.

abdominal sepsis in ICU, but also to the planning of actions aimed at improving the quality of care for these patients. patients, and may also be an important tool to qualify the clinical practice itself, thus reflecting the reduction of mortality in these patients.

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Corresponding Address

Natasha Varjão Volpáti

E-mail: naty_volpati@hotmail.com

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