Cross-cultural adaptation and content validity evidence of the Brazilian version of the Nociception Coma Scale-revised

Adaptação transcultural e evidência de validade de conteúdo da versão brasileira da Nociception Coma Scale-revised

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ABSTRACT

BACKGROUND AND OBJECTIVES: There are communication barriers to assess pain in patients with consciousness and cognitive disorders. This study aimed to make the cross-cultural adaptation of the Nociception Coma Scale-Revised (NCS-R) to the Portuguese language and check the validation evidence of the content of the NCR-R Brazilian version in non-communicative patients with consciousness and cognitive disorders.
METHODS: This is a methodological study to check the cross-cultural adaptation of the NCR-R, divided into two stages: cross-cultural adaptation and check of the content validity. The cross-cultural adaptation phase included an initial translation, synthesis of translations, back-translation, expert committee, and cognitive debriefing based on Beaton and Price. A second expert committee evaluated the translated and adapted version to check the content validity index
RESULTS: The NCS-R scale was translated and cross-culturally adapted, presenting good evidence of content validity with a Content Validity Index of 0.86.
CONCLUSION: The NCS-R is translated and transculturally adapted and has good evidence of content validity.
Keywords: Consciousness disorders, Pain, Psychometrics, Nursing assessment, Validation studies.

RESUMO

JUSTIFICATIVA E OBJETIVOS: Em pacientes com desordens de consciência e distúrbios cognitivos há barreiras de comunicação para a avaliação da dor. O objetivo deste estudo foi realizar a adaptação transcultural da *Nociception Coma Scale-revised* (NCS-R) para a língua portuguesa e verificar as evidências de validade de conteúdo da versão brasileira da NCS-R em pacientes não comunicativos com desordens de consciência e distúrbios cognitivos.
MÉTODOS: Estudo metodológico para adaptação transcultural da NCS-R dividido em duas etapas*:* adaptação transcultural e verificação da validade de conteúdo. A fase de adaptação transcultural incluiu a tradução inicial, síntese das traduções, retrotradução, comitê de especialista e *debriefing* cognitivo baseado em Beaton e Price. A versão traduzida e adaptada foi avaliada por um segundo comitê de especialistas para a avaliação do índice de validade de conteúdo**.**
RESULTADOS: A escala NCS-R foi traduzida, adaptada do ponto de vista transcultural e apresentou boa evidência de validade de conteúdo com Índice de Validade de Conteúdo de 0,86.
CONCLUSÃO: A NCS-R encontra-se traduzida e adaptada do ponto de vista transcultural, e possui boa evidência de validade de conteúdo.
Descritores: Avaliação em enfermagem, Dor, Estudos de validação, Psicometria, Transtornos da consciência.

INTRODUCTION

Pain is defined as sensorial and emotional experience, normally caused by a real or potential tissue lesion, and each individual learns to use this term based on their previous experiences. Besides generating significant physical and emotional stress to patients and their caregivers, pain has a negative economic and social impact[1].
In this sense, self-report is considered the gold standard to assess pain. However, with non-communicative patients, for example, sedated patients, patients in mechanical ventilation, and with severe neurological lesions, it is necessary to have observational instruments to identify the symptom[2].
In patients with severe neurological lesions and consciousness disorders, the most used term is nociception assessment, which is defined as the neural coding process and the processing of the noxious stimulus[3,4], that is mediated by lateral and medial brain

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connections with differentiation between the areas involved in the perception of pain versus the suffering related to the consciousness of the perception of the pain in question[5,6]. It is related to the sensitive-discriminative dimension that activates the lateral pain system, including lateral portions of the thalamus, primary (S1) and secondary (S2) somatosensory cortex, and insula[7,8].

Concerning the medial pain system, the descending connections of the anterior cingulate cortex, the medial region of the thalamic nuclei and periaqueductal gray, act on the modulation of the response to the noxious stimulus. The cingulate gyrus, the cerebellar tonsil, hippocampus, hypothalamus, locus coeruleus, orbitofrontal cortex, and prefrontal cortex have a role in the pain-related affective behavior[7]. The interconnectivity between the periaqueductal gray and the orbitofrontal cortex is associated with the cognitive and emotional responses in the presence of pain[7].

Therefore, the integration of several areas of the brain due to a noxious stimulus characterizes pain, according to Melzack, as a cognitive-evaluative, affective-motivational, and sensory-discriminative response[9]. Although most of today's evidence point to the fundamental role of the thalamus-cortex interaction that characterizes pain as a conscious experience, there are some questions in relation to patients with consciousness disorders[7,9].

A study using positron emission tomography-computed tomography (PET-CT) investigated the responses to the processing of pain in patients with Unresponsive Wakefulness Syndrome (UWS) and healthy individuals, showing an increase in blood flow in the regions of the midbrain, contralateral thalamus, and that probably, patients in vegetative state do not feel the painful stimuli in an integrative and conscious manner[7,8].

On the other hand, smaller and more recent studies showed different results with the activation of S1, S2, anterior cingulate cortex and insula, areas related with the affective dimension of pain, indicating that despite the alteration, it is possible to have the perception of pain in some patients in a vegetative state, even when compared to patients with a minimum state of conciousness[7].

Another interesting point is that due to the complexity and clinical variations, a considerable number of patients diagnosed as in a vegetative state were, in fact, in a state of minimal consciousness, emphasizing the importance of using the correct instruments to assess and treat pain in patients with consciousness disorders properly[9].

The first instrument to assess nociception in patients with consciousness disorders was the Nociception Coma Scale (NCS), developed by study[3] The NCS was developed from observations that suggest painful behaviors with four items: motor, verbal, visual and facial expression response, with scores where zero means the absence of response in the face of a nociceptive stimulus and 12 is the maximum response in the face of a nociceptive stimulus[3].

A later study using the NCS in 64 patients showed higher scores in the face of nociceptive stimuli in terms of verbal, motor, and facial expression responses, suggesting good results regarding sensitivity. However, the item visual response did not present any difference. In light of these results, the authors proposed the Nociception Coma Scale-Revised (NCS-R) with scores from zero to nine, but there is still no consensus on the cut-off point[10].

Given the relevance to research and clinical practice, studies about the use of the NCS-R are necessary. In this sense, it is believed that translation, transcultural adaptation, and check of the evidence on content validity of the NCS-R in the national context would provide the necessary input to make the clinical decision for the population at hand.

The objective of this study was to perform the transcultural adaptation and check the evidence on content validity of the Brazilian version of the NCS-R.

METHODS

Its is a methodological study to adaptation of the NCS-R. Caroline Schnakers, the author, authorized the transcultural adaptation process via electronic mail. The study was conducted from February to August 2019.

The transcultural adaptation was based on studies[11,12], and it had the following phases: translation, translation synthesis, back-translation, experts' committee, submission of the adapted version to the author, and cognitive debriefing.

As in previous studies for the transcultural adaptation of the NCS-R, it was decided not to perform the pre-test but the cognitive debriefing[11-13] instead.

The translation was performed by two translators invited to participate by electronic mail, and upon acceptance, the instrument was sent by email.

Translator (T1) is Brazilian, a health professional with proficiency in English and experience in the subject of the study, which provided the translation version T1 with greater scientific similarity with the instrument. Translator (T2) is an English teacher, with no background in the health area, and produced the translation version T2.

The translation synthesis was performed by a Brazilian translator, English teacher with no background in the health area, and later sent to translators T1 and T2. At the end of this step, we obtained the synthesis version T1-T2.

Two American translators, English teachers, proficient in Brazilian Portuguese, performed the back-translation and versions BT1 and BT2.

An experts' committee was created to evaluate the semantic, idiomatic, conceptual, and experimental equivalences, following the criteria of knowledge about the transcultural adaptation process, master English and Portuguese languages, and knowledge related to the subject in question[11].

Fifteen invites were sent to participate in the committee, via electronic mail, and the acceptance was formalized by signing the Free and Informed Consent Term (FICT) by the participants.

The experts' committee comprised of one psychometrician, one neurologist, one of the translators (T1), one anesthesiologist specialized in pain, and one nurse specialized in intensive care[11]. Upon acceptance, the instruction forms to evaluate the instrument were sent together with a spreadsheet containing the original, the translated versions (T1 and T2), the synthesis (T12), and the two back-translations (BT1 and BT2).

The version produced in this phase was analyzed by the researchers following the agreement criteria among the experts with

their suggestions for the items considered questionable or inadequate. The version resulting from the experts' committee was submitted to the author of the scale via electronic mail.

After the submission, a second experts' committee was created to evaluate the content validity. Twenty-five invites were sent by electronic mail directed to professionals following the criteria on knowledge about the subject and knowledge about the transcultural adaptation process and evaluation of the evidence of content validity.

The acceptance to participate in the committee was also formalized by signing the FICT. The committee comprised of three Ph.D., one physician, two nurses, two masters in nursing, and two specialized nurses. After the acceptance, the researcher sent, via electronic mail, a form with instructions to complete the evaluations and a spreadsheet with the original and pre-final versions of the NCS-R in Brazilian Portuguese.

Four health professionals were invited for the cognitive debriefing: three nurses and one nursing technician who had a 1-hour training to apply the pre-final version in 24 patients with consciousness disorders[12,14,15].

The descriptive statistics were used to analyze the data to characterize the subjects. Values above 0.78 of the Content Validity Index (CVI) were considered acceptable for agreement in the items clarity, essentiality, and relevancy among the experts, and the response options were not clear, somewhat clear, clear, very clear[16].

The authorization to conduct the study was requested to the Institute of Teaching and Research of the Hospital Sírio-Libanês, and subsequently, the project was submitted to the Research Ethics Committee of the Institution. Data collection started after the approval of this project by the Research Ethics Committee (CAAE: 05557018.9.0000.5461)

RESULTS

The scale has only three items that are similar to the behavioral questions described in other parameters of the neurologic assessment.

Table 1 shows the versions of the first three steps of the adaptation process of the NCS-R: Br version.

A third translator analyzed the two translations, and it was observed that the version of the translator T1 was, in general, more adequate. Among the adjustments, it was suggested for the "Motor response" item, subitem Withdrawal in flexion, in item "Verbal response" subitem Oral reflex/fright response. These items were also considered questionable by the experts' committee.

Translations were submitted to the author's analysis, Dr. Schnakers, who disagreed with the back-translation of the subitem "Oral reflex/fright response," and provided the Application Manual of the NCS-R suggesting to refer to it for term adequacy. Upon these suggestions, the researcher and the adviser reviewed the translation synthesis and the back-translations, and the subitem was changed to "Oral reflex/involuntary oral movements." It was again submitted to the author and approved, and then evaluated by a new experts' committee; The results presented below relate to the equivalence evaluation and content validity (Tables 2 and 3).

When the experts checked the agreement index concerning the equivalences, it was observed that the instrument had CVI values

Table 1. Description of the versions produced by the translation, synthesis, and back-translation of the NCS-R. São Paulo, 2019.

	Translation T1	Translation T2	Suggestion - Synthesis T-12	Back-translation BT1	Back-translation BT2
Title	*Escala de nocicepção no coma - revisada*	*Escala de nocicepção no coma - revisada*	*Escala de nocicepção no coma - revisada*	Nociception Coma Scale - Revised	Nociception Coma Scale - Revised
	Resposta motora	*Resposta motora*	*Resposta motora*	Motor response	Motor response
Items	*3. Localiza estímulo doloroso*	*3. Localização para estímulo doloroso*	*3. Localização do estímulo doloroso*	3. Localization for painful stimulus	3. Localization for painful stimulus
	2: Retirada do estímulo doloroso	*2: Retirada de flexão*	*2: Retirada em flexão*	2: Move by flexion	2: Withdrawal of flexion
	1 Postura anormal*	*1* Pose anormal*	*1* Postura anormal*	1* Abnormal posture	1* Abnormal posture
	0 Nenhuma/relaxada	*0 Nenhuma/flácida*	*0 Nenhuma/flácida*	0 None/flaccid	0 None/flaccid
	Resposta verbal	*Resposta verbal*	*Resposta verbal*	Verbal response	Verbal response
Items	*3. Verbalização (compreende)*	*3. Verbalização (inteligível)*	*3. Verbalização (inteligível)*	3. Verbalization (intelligible)	3. Verbalization (intelligible)
	2: Emite sons (não específico)	*2: Vocalização*	*2: Emite sons*	2: Emits sounds	2: Emits sounds
	1 Gemido*	*1* Gemidos*	*1* Gemidos*	1* Groans	1* Moans
	0 Nenhuma	*0 Nenhuma*	*0 Nenhuma*	0 None	0 None
	Expressão facial	*Expressão facial*	*Expressão facial*	Facial expression	Facial expression
Items	*3. Choro*	*3. Choro*	*3. Choro*	3. Crying	3. Cry
	2: Careta/franzir de testa	*2: Careta*	*2: Careta*	2: Grimace	2: Grimace
	1 Espanto/susto*	*1* Reflexivo oral/resposta de susto*	*1* Reflexivo oral/resposta de susto*	1* Oral reflex/fright response	1* Oral reflex/fright response
	0 Nenhuma	*0 Nenhuma*	*0 Nenhuma*	0 None	0 None

Table 2. Result of the equivalence evaluation by the experts' committee. São Paulo, 2019

Items		Total of agreement*			
		Semantics	Idiomatic	Conceptual	Experimental
1	Nociception coma scale - revised (Br)	1.00	1.00	1.00	1.00
2	Motor response	1.00	1.00	1.00	1.00
3	Localization of the painful stimulus (=3)	1.00	1.00	1.00	1.00
4	Withdrawal in flexion (=2)	1.00	1.00	1.00	1.00
5	Abnormal posture (=1)	1.00	1.00	1.00	1.00
6	None/flaccid (=0)	1.00	1.00	1.00	1.00
7	Verbal response	1.00	1.00	1.00	1.00
8	Verbalization (intelligible) (=3)	1.00	1.00	1.00	1.00
9	Vocalization (=2)	1.00	1.00	1.00	1.00
10	Groans (=1)	1.00	1.00	1.00	1.00
11	None (0)	1.00	1.00	1.00	1.00
12	Facial expression	1.00	1.00	1.00	1.00
13	Crying (=3)	1.00	1.00	1.00	1.00
14	Grimace (=2)	1.00	1.00	1.00	1.00
15	Oral reflex/involuntary oral movements (=1)	0.86	0.86	0.86	0.86
16	None (0)	1.00	1.00	1.00	1.00

* CVI = Content Validity Index.

Table 3. Results of the content validity index by the experts' committee. São Paulo, 2019

Items		Total of agreement*		
		Clarity	Essentiality	Relevancy
1	Nociception coma scale - revised (Br)	1.00	1.00	1.00
2	Motor response	1.00	1.00	1.00
3	Localization of the painful stimulus	1.00	1.00	1.00
4	Withdrawal in flexion	1.00	1.00	1.00
5	Abnormal posture	1.00	1.00	1.00
6	None/flaccid	1.00	1.00	1.00
7	Verbal response	1.00	1.00	1.00
8	Verbalization (intelligible)	1.00	1.00	1.00
9	Vocalization	1.00	1.00	1.00
10	Groans (=1)	1.00	1.00	1.00
11	None (0)	1.00	1.00	1.00
12	Facial expression	1.00	1.00	1.00
13	Crying (=3)	1.00	1.00	1.00
14	Grimace (=2)	1.00	1.00	1.00
15	Oral reflex/involuntary oral movements (=1)	0.86	0.86	0.86
16	None (0)	1.00	1.00	1.00

* CVI = Content Validity Index.

close to 1, that is, it presented satisfactory results in agreement with the criteria and values accepted as reference. The cognitive debriefing was performed by three nurses and one nurse technician who had a 1-hour training to apply the pre-final version in 24 patients. No need for adjustments in the produced version was identified (Table 4).

Table 4. Pre-final version of the Nociception Coma Scale-Revised (Br), São Paulo, 2019

Motor response
Localization of the painful stimulus (=3)
Withdrawal in flexion (=2)
Abnormal posture (=1)
None/flaccid (=0)
Verbal response
Verbalization (intelligible) (=3)
Vocalization (=2)
Groans (=1)
None (0)
Facial expression
Crying (=3)
Grimace (=2)
Oral reflex/involuntary oral movements (=1)
None (0)

DISCUSSION

Pain is a subjective experience, and the patient's self-report is considered the gold standard to assess pain. However, in an environment of patient care, pain assessment is a challenge since many times they are unable to communicate[3,15].

Over the last decades, we have seen many efforts to develop specific and accurate instruments to facilitate pain identification in non-communicative patients, since pain management can improve the outcomes for these patients [3]. In acute or chronic stages of patients with severe brain lesions, there are situations that can lead to pain, mainly during care and mobilization[6,7].

In a study using neuroimaging, the authors suggested that there is the preservation of the capacity to perceive pain in patients in minimum consciousness estate, and in some patients in a vegetative state, reinforcing the need to assess and manage pain[5].

This study followed all the steps of the NCS-R transcultural process recommended by Beaton[11], except for the pre-test; however, the cognitive debriefing, according to Price[12], was used instead. In another NCS-R transcultural adaptation study, the pre-test was not performed for being considered that the terms used in the item were widespread in the clinical practice for this population[17]. The content validity assessment of the NCS-R indicated satisfactory values for all items and response options[16].

It is worth mentioning that the score of the oral reflex/involuntary movements option was above the desired, but the lowest index in agreement, indicating some fragility in the response option.

This result can be explained by the more direct correspondence between the item facial expression and the grimace response option compared with the oral reflex/involuntary movements that can be considered a non-specific descripton[17]. Other authors conducted studies with patients with consciousness disorders and described grimace as the most characteristic aspect of facial pain expression[15,17,18].

The understanding of the essence of the construct and the purpose of an observational instrument of pain are necessary, since the score indicates the presence or absence of a painful behavior, suggesting that this instrument should be assessed based on the clinimetric point of view[15,19].

One of the highlights of this study is the availability of an instrument that provides evidence of the content validity to assess pain in a population where pain is under-identified and, therefore, not managed.

A limitation of the study is that the pre-test was not performed.

CONCLUSION

It was possible to adapt the NCS-R to the Brazilian Portuguese language. The tests performed showed that the NCS-R provides adequate evidence of the content validity. Further studies should be performed to confirm these findings and expand the evaluation of the validity evidence of the version of the scale in our practice.

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