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CULTURAL ADAPTATION AND CONTENT VALIDITY OF MEDICAL ADHESIVE-RELATED SKIN INJURY FOR PORTUGUESE IN BRAZIL

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ABSTRACT

Objective: To culturally adapt the Medical Adhesive Related Skin Injury (MARSI) classification instrument to the Brazilian Portuguese and test the content validity of the adapted version. **Method:** Three phases comprised the cultural adaptation: translation, evaluation by a committee of judges composed of ten stomal therapists and back-translation. The project was approved by the Research Ethics Committee of the University of São Paulo. **Results:** A Portuguese version of the instrument was obtained after translation, which was guided by the Likert scale. The controversial and divergent terms were discussed by the committee of judges and their content was validated in a focus group, generating a content validity index of 0.9. The version was back-translated and approved by one of the instrument's developer, who just suggested an adaptation to the concept of allergic contact dermatitis. **Conclusion:** The translated and culturally adapted version of MARSI classification instrument was obtained and its content validity attested. Tests regarding inter- and intra-observer reliability and concurrent validity are needed.

DESCRIPTORS: Validation studies. Skin injury. Adhesive tape. Enterostomal therapy.

ADAPTAÇÃO CULTURAL E VALIDADE DE CONTEÚDO DO INSTRUMENTO DE CLASSIFICAÇÃO MEDICAL ADHESIVE-RELATED SKIN INJURY PARA O PORTUGUÊS DO BRASIL

RESUMO

Objetivo: Adaptar culturalmente o instrumento de classificação da *Medical Adhesive Related Skin Injury* (MARSI) para a língua portuguesa no Brasil e testar a validade de conteúdo da versão adaptada. **Método:** Três fases compuseram a adaptação cultural: tradução, avaliação por comitê de juízes composto por dez estomaterapeutas e retrotradução. O projeto foi aprovado pelo comitê de ética em pesquisa. **Resultados:** Uma versão em português do instrumento foi obtida após tradução, sendo guiada pela escala tipo Likert. Os termos polêmicos e divergentes foram discutidos pelo comitê de juízes e tiveram o conteúdo validado por meio de reunião virtual em grupo focal, resultando em um índice de validade de conteúdo de 0,9. A versão foi retrotraduzida e aprovada por uma das autoras do instrumento, que sugeriu apenas adequação do conceito de dermatite de contato alérgica. **Conclusão**: Considera-se obtida a versão adaptada culturalmente do instrumento de classificação da MARSI, com sua validade

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de conteúdo atestada. Serão necessários novos estudos para testar demais propriedades de medida da versão adaptada como confiabilidade inter e intraobservadores e validade concorrente.

DESCRITORES: Estudos de validação. Ferimentos e lesões. Adesivos médicos. Estomaterapia.

ADAPTACIÓN CULTURAL Y VALIDEZ DE CONTENIDO DE LA HERRAMIENTA MEDICAL ADHESIVE-RELATED SKIN INJURY PARA PORTUGUÉS EN BRASIL

RESUMEN

Objetivo: Adaptar culturalmente el instrumento de clasificación MARSI - Lesiones cutáneas relacionadas con adhesivos médicos al idioma portugués en Brasil y probar la validez de contenido de la versión adaptada. **Método:** Tres fases comprendieron la adaptación cultural: traducción, evaluación por un comité de jueces compuesto por diez terapeutas estomales y retrotraducción. El proyecto fue aprobado por el Comité de Ética en Investigación de la Escuela de Enfermería de la Universidad de São Paulo. **Resultados:** se obtuvo una versión portuguesa del instrumento después de la traducción, guiada por la escala Likert. Los términos polémicos y divergentes fueron discutidos por el comité de jueces y su contenido fue validado en un grupo focal, generado a un índice de validez de contenido de 0.9. La versión fue traducida al revés y aprobada por el Dr. MCNichol, quien solo sugirió una adaptación al concepto de "dermatitis alérgica de contacto". **Conclusión:** Se considera obtenida la versión traducida y adaptada culturalmente del instrumento de clasificación MARSI, con su validez de contenido atestiguada. Se necesitarán pruebas de confiabilidad interobservador e intraobservador y validez concurrente.

DESCRIPTORES: Estudios de validación. Lesion de piel, Adhesivos médicos. Estomaterapia.

INTRODUCTION

Medical Adhesive-Related Skin Injury (MARSI) was described for the first time during the *1º Interpele: Simpósio de Estratégias de Prevenção da Integridade da Pele* ("1st Interskin: Symposium on Skin Integrity Prevention Strategies"), held in Angra dos Reis, Brazil, in March 2011[1]. From then on, it was defined by McNichol and colleagues[2] as an erythema or other manifestation of skin abnormality, including, but not limited to, vesicles, blisters, erosion, or rupture of the skin persisting for 30 minutes or more after removal of the patch.

This injury category is frequent but undervalued, potentially impacting patient outcomes, satisfaction and safety[3]. Several intrinsic and extrinsic factors influence the development of MARSI. One of the factors associated with its occurrence is related to increased skin fragility. Individuals at the extremes of age, with mobility problems, cancer patients, diabetics, cardiovascular diseases, dermatological disorders (for example eczema, chronic ulcers, epidermolysis bullosa) or hematological conditions, in addition to conditions such as dehydration, malnutrition, dry skin, edema, exposure to humidity, radiotherapy, photoaging, use of corticosteroids, anti-inflammatories, anticoagulants and previous use of medical adhesives become more vulnerable to the appearance of these lesions. Despite all these predisposing conditions, any individual using skin patches can develop them[3-9].

MARSI can cause significant pain and distress, contributing to prolonged hospital stays, increased healthcare professional care time, increased use of dressings, and increased risk of complications, including infection. Therefore, appropriate prevention protocols are necessary to ensure the correct choice of adhesive and proper application and removal techniques[5].

The epidemiology of MARSI is still scarce due to the lack of records in medical records, the lack of knowledge among professionals about this type of injury, and the lack of protocols and public policies for the systematization of its prevention, early detection and treatment[5].

The incidence and prevalence of MARSI varies according to the health service. In an intensive care unit in China, the incidence was 11.8%, with denudation of the epidermis responsible for 72.7% of cases[10]. Another study carried out in

China with cancer patients admitted to inpatient units identified a prevalence of 19.7% of MARSI, with transparent film as the primary causative agent and irritant contact dermatitis as the cause of the highest number of occurrences[7]. A study conducted in an outpatient vascular clinic in the United States with 120 adult patients diagnosed with peripheral vascular disease found a prevalence of 5.8% (7/120)[11]. In non-critical hospitalization units with 65 beds, the authors evaluated the skin of all patients for 28 consecutive days, finding an average prevalence of 13% (3.4 to 25%)[12]. In a Japanese long-term care facility, the incidence of MARSI was 15.5% (24/155), and the types of injuries observed were irritant contact dermatitis (70.6%), friction injury (20.6%) and folliculitis (8,8%)[13]. Another scenario in which the incidence was documented was orthopedic surgery, with tension or blister injuries frequently observed (10 to 41%) resulting from large quantities of medical adhesives to maintain compression bandages. The risk of damage caused by the adhesive is aggravated by joint movement, skin friction and the presence of tissue edema[14]. In neonatal and pediatric ICUs, the prevalence of MARSI was 26.6%[15] in Jordan and, on average, 37.1%, ranging from 23.5% to 54.1% in China[16].

In Brazil, the incidence of MARSI has been recorded. In a coronary unit in Minas Gerais, with a sample of 83 patients followed up for up to fifteen days after admission, this type of injury occurred in 25.3% of them[17]. A cross-sectional study of 123 patients admitted to cardiac Intensive Care Units (ICUs) of two hospitals in São Paulo identified a point prevalence of 22.7% (28/123) of MARSI[18]. A multicenter study with 377 critically ill patients identified a prevalence of 16.2%, with 11.5% in ICUs in public hospitals, 12.0% in private hospitals and 21% in university hospitals. MARSI was mainly caused by mechanical trauma, and the predominant subtype was denudation of the epidermis (46.3%), followed by friction injury (31.3%). The most affected regions were the chest (23.8%) and abdomen (20.8%), and the majority of injuries were caused by transparent films (44.8%), microporous tape (20.9%) and electrodes (14.8%)[19].

In addition to the repercussions for the patient, there are economic repercussions for health services. A German study found that the total average cost for treating MARSI was €82.24 per patient per incident, including all treatment materials and nursing time for the healing period and documentation[20]. In Brazil, these costs are unknown.

Aiming to systematize the classification and evaluation of MARSI, a group of North American researchers and members of the skin integrity council of the company 3M developed an instrument that, although it does not yet have tested measurement properties, has been widely used in international studies (Fig.1).

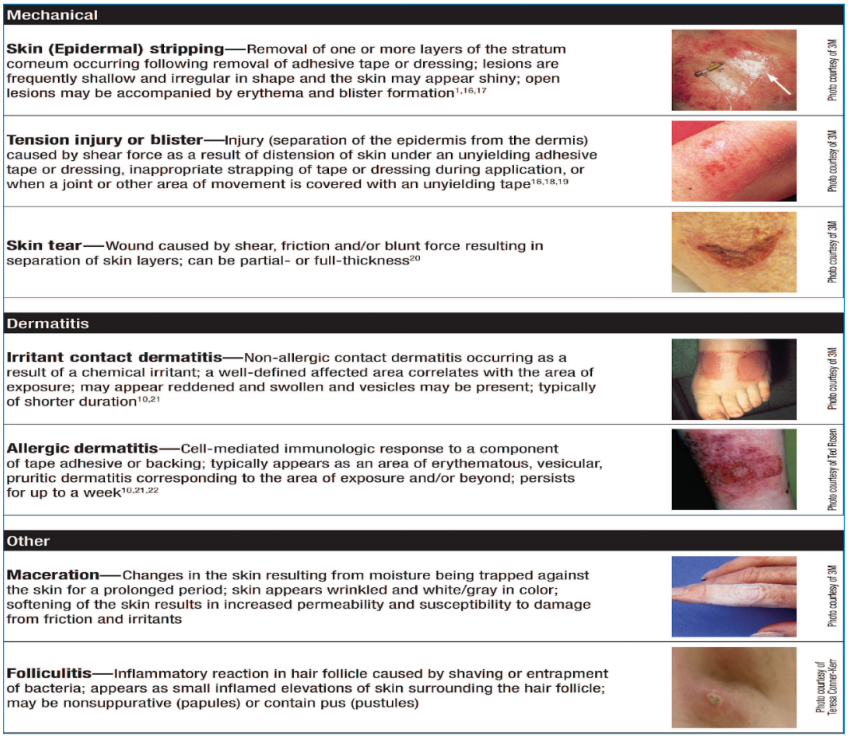

Figure 1. English version of the MARSI classification instrument
McNichol L, Lund C, Rosen T, Gray M. Medical adhesives and patient safety: State of the science consensus statements for the assessment, prevention, and treatment of adhesive-related skin injuries. J Wound, Ostomy Cont Nurs. 2013;40(4):365–80.Reproduction Authorized by the main author.

The instrument resulted from a discussion process held in December 2012 in Minnesota, United States, led by Laurie Mc Nichol, Carolyn Lund, Ted Rosen and Mikel Gray. This MARSI classification instrument provides simple definitions and technical terms, allowing their incorporation into clinical practice.

Given the availability of this instrument and the scarcity of Brazilian literature on the topic, which leads to underreporting and a bottleneck in expanding knowledge about MARSI, we decided to develop the present study. Adapting and validating a simple and accessible international classification system will allow a common systematized language, facilitating communication between health professionals, the most appropriate planning of the assistance to be provided, and comparing the results of our publications with those achieved by international authors.

The objective of this study is to culturally adapt the MARSI classification instrument to the Portuguese language in Brazil and test the content validity of the adapted version.

METHOD

The present is a methodological study with a quantitative approach to the cultural adaptation of the MARSI classification instrument into Brazilian Portuguese and the content validity of the adapted version since this measurement property has already been tested during this process. The selected methodology includes three stages: translation, content analysis and validation by a committee of judges and back-translation[21].

Translation

Firstly, two Brazilian translators fluent in English translated the MARSI classification instrument: a layman in the health field with no knowledge of the research project and a nurse aware of the study's objective. These translations were called T1a and T1b, respectively. After receiving the two translated versions, a single version was written by a third translator, Brazilian, fluent in English, linked to the health area. This translation was called T1c.

To systematize the work, the translators received a translation table and the original English version of the MARSI classification instrument broken down item by item via email. For each item, the translator filled out the table with the appropriate translation, indicating the degree of difficulty found based on a Likert-type scale, whose values ranged from 0 to 10, in which 0 corresponded to the absence of difficulty and 10 to the greatest Difficulty level. Furthermore, translators were asked to justify the abovementioned difficulty and include pertinent comments.

Judges' committee analysis

Then, the translated T1c version was analyzed by a committee of judges composed of ten nurses specializing in stomatherapy, fluent in English, experienced in treating skin lesions and knowledgeable in the fundamentals of the instruments. The selected committee of judges has experience in the adaptation and validation processes of measurement instruments and is a fundamental part of achieving intercultural equivalence of the translated instrument. The evaluation of translated instruments aims to analyze semantic (grammatical and vocabulary), idiomatic (specific colloquial expressions, rarely translatable, requiring replacement with equivalent expressions), cultural (coherence between the terms used and the culture of the population) and conceptual (maintenance of the original concepts of the translated terms) between each item of the translated version and the original[21]. Each judge analyzed the four dimensions described using the 5-point Likert scale, in which (1= strongly disagree; 2= disagree; 3= no opinion; 4= agree; 5= strongly agree) at each translation stage. In addition to these analyses, the committee of judges verified the clarity and representativeness of the instrument. Regarding clarity assessment, judges were asked for suggestions for adapting the wording and assessing representativeness. Judges were asked whether the items reflected the concepts involved and originally proposed, through prior knowledge of skin lesions, with freedom for improvements required for each item.

After receiving the judges' individual analyses, there was a need to discuss the controversial and controversial aspects highlighted. Therefore, the principal author coordinated a four-hour meeting with two inter-observers and seven members of the committee of judges (called focus groups) to establish a final version (T2). The agreement between the judges' answers was analyzed using the content validity index (CVI), obtained with the proportion of items that received a score of 4 or 5 from the judges[22-24].

It is increasingly common to use a group of independent experts to assess the content validity of new instruments. The CVI indicates the extent to which experts' opinions are congruent, measuring the proportion or percentage of judges who agree on aspects and items of the instrument. In addition to analyzing the items, it allows analyzing the instrument as a whole. Excellent content validity of a scale is achieved with a CVI ≥0.8[23].

Back translation

The T2 version prepared by the focus group was sent for back-translation, produced by a lay translator in the health area, fluent in Portuguese and whose mother tongue was English. For each item, the translator filled out the table with the appropriate translation, indicating the difficulty found using a Likert scale, from 0 to 10, with 0 corresponding to the absence of difficulty and 10 to the greatest degree of difficulty. Furthermore, he was asked to justify the difficulty highlighted and include pertinent comments. This back-translated version was sent to the original author of the instrument to confirm the equivalence between the original and adapted versions.

The results obtained from the Likert scale were compiled and grouped into Excel spreadsheets and analyzed using the Statistical Package for Social Sciences (SPSS) version 23.0.

Authorization was first formalized to carry out the study, which Dr. Laurie McNichol, the principal author of the instrument, granted. The Research Ethics Committee of the School of Nursing of the University of São Paulo approved the research project under number CAAE: 26282619.8.0000.5392; opinion 3,780,925. The nurses who made up the committee of judges and participated in the translation stages were included in the sample only after consent and guarantee of anonymity.

RESULTS

The results are presented according to the methodological stage.

Translation

Three versions of the instrument in Portuguese were obtained (T1a, T1b, T1c). For the lay translator in the health area (T1a), six of the eleven instrument items presented difficulty level 5, due to the use of technical terms, which a lack of knowledge in the health area can explain. As for the specialist translator (T1b), two items of the instrument raised conceptual doubts, presenting difficulty level 5: "medical adhesive" and "skin (Epidermal) stripping". The specialist translator (T1c), who unified the T1a and T1b translations, reported level 3 difficulty translating the term medical adhesive and the entire item "tension injury or blister". According to them, the last item could be confused with the superficial skin removal item, as both mention the formation of blisters. She also marked difficulty level 4 when translating the term "backing" in the item "allergic dermatitis".

Judges' committee analysis

The overall average CVI was 0.9 (Table 1).

The terms with lower CVI values (0.7 and 0.8) are associated with the title of the instrument and the items of the subtype *tension injury or blister* and *allergic irritant dermatitis*, resulting in the need for adjustments, which the focus group carried out.

Table 1. Content Validity Index (CVI) of version T1c, unified from versions T1a and T1b. São Paulo, SP, Brasil, 2020.

Items	CVI
Instrument title	0.7
Type *Mechanical*	0.9
Subtype *Skin (Epidermal) stripping*	0.9
Subtype *Tension injury or blister*	0.8
Subtype *Skin tear*	0.9
Type *Dermatitis*	1
Subtype *Irritant contact dermatitis*	1
Subtype *Allergic dermatites*	0.8
Type *Other*	1
Subtype *Maceration*	1
Subtype *Folliculitis*	1

The word "medical adhesive" generated significant disagreement between judges and translators, reducing the IVC values. Some judges suggested the terminology "adhesive supplies" (*insumos adesivos*), as adhesives are not for the exclusive use of doctors. However, after discussion with the focus group, the selected translation was "medical adhesives" (*adesivos médicos*) as it is a term known and accepted in Brazil as the expression *lesão por pressão relacionada a dispositivo médico* (medical device-related pressure injury).

Another essential item of discussion was the terminology "*skin (epidermal) stripping*", which led some judges to suggest the use of *remoção superficial da pele (epiderme)*, also being modified during the discussion in the focus group. In the end, it was adopted "denudation of the epidermis" (*desnudação da epiderme*).

Back translation

In the back-translation, the translator reported level 7 difficulty on the Likert scale in three of the eleven items. Some minor differences between the original and back-translated versions were identified. However, these did not compromise the equivalences obtained in the previous stage. After sending the back-translated version to one of the authors of the original instrument, she suggested that the mention of time (persists for up to a week) of the allergic contact dermatitis subtype be excluded, as this condition can continue for more than a week. In the adapted version of the MARSI classification instrument, its final title was *Classificação de lesão de pele relacionada a adesivos médicos* (Classification of skin lesions related to medical adhesives), which was also approved by the original author of the instrument. The adapted instrument with content validation is presented in Table 2.

Table 2. MARSI assessment and classification instrument - Version adapted to Portuguese with content validation. São Paulo, SP, Brasil. 2020.

Item	Final T2 version
Title	Classification of skin injury related to medical adhesives
Type	Mechanic
Subtypes	Epidermis denudation: Removal of one or more layers of the stratum corneum after removing a medical adhesive; the lesions are often superficial and irregularly shaped, and the skin may appear shiny; open lesions may be accompanied by erythema and blistering.
	Tension Injury or Blister: Separation between epidermis and dermis caused by shear force due to stretching of the skin under a medical adhesive, during improper tape application, or when an inflexible adhesive covers a joint or other movement area.
	Friction injury: Injury caused by shear, friction and/or brute force, resulting in the separation of skin layers. This separation can be partial or full thickness.

Continue...

Tale 2. Continuation..

Item	Final T2 version
Type	Dermatitis
Subtypes	Irritant contact dermatitis: Non-allergic contact dermatitis occurs as a result of skin contact with a chemical irritant; has a well-defined affected area that corresponds to the exposure area; may appear hyperemic and edematous, vesicles may be present; generally short-lived.
	Allergic contact dermatitis: Cellular immunological response to a component of the medical patch or one of its components. It usually appears as an area of erythematous, vesicular, or pruritic dermatitis, which may extend beyond the exposed area.
Type	Others
Subtypes	Maceration: Change in the skin resulting from direct and prolonged contact of the skin with moisture; the skin appears wrinkled and has a whitish/grayish color; Softening of the skin results in increased permeability and susceptibility to damage from friction and irritants.
	Folliculitis: Inflammatory reaction in the hair follicle, caused by hair removal or microbial infection; appears as small inflamed elevations of the skin around the hair follicle; they may be non-suppurative (papules) or with purulent content (pustules).

DISCUSSION

The present study obtained the adapted version of the MARSI classification instrument into Brazilian Portuguese, as well as attesting the validity of the content of this version.

After proceeding with the methodological steps established by Beaton[21], Overcoming the difficulties of the translators and experts who made up the committee of judges, the instrument discussed in the focus group obtained CVI levels above 80%. To achieve this recommended score, the itens "dermatite" (dermatitis), "dermatite de contato alérgica" (allergic contact dermatitis), "outros" (others), "maceração" (maceration), "foliculite"(folliculitis) obtained 100 % agreement, and the items "mecânico" (mechanical), "desnudação da epiderme"(denudation of the epidermis), "lesão por fricção" (friction injury), 90% de concordância. 90% agreement. "lesão por tensão ou bolha" (tension injury or blister) e "dermatite de contato alérgica"(allergic contact dermatitis) obtained 80% agreement. This finding may be due to the wide dissemination of these terms in the judges' daily professional lives.

Regarding the title of the instrument (*Medical Adhesive Related Skin Injury Classification*), it also required intense discussion in the focus group, reaching 70% agreement between judges in the first analysis. There was concern about the association of this category of injuries with the medical professional category. As described in the previous section, some authors have suggested using "adhesive supplies" instead of "medical adhesives". However, during the focus group discussion, it was concluded that "medical adhesives" would be more appropriate for clinical practice, as "medical devices" are already used in this area.

After approval of the back-translation by one of the authors of the original version of the instrument, followed by minor adjustments, the content validity of the final Brazilian Portuguese version of the instrument for classifying skin lesions related to medical adhesives was considered attested.

No adapted version with content validity has been found in another language, but rather non-validated free translations. It is still necessary to evaluate the other measurement properties of the instrument in its version adapted to Brazilian Portuguese.

CONCLUSION

Although some instrument items disagreed with the translations and back-translations, the equivalences obtained remained strong. The creation of the focus group enabled broad discussion and satisfactory agreement.

The MARSI classification was culturally adapted to Brazilian Portuguese, and its content was validated. Other studies will be necessary to test other measurement properties of the adapted version, such as inter- and intra-observer reliability and concurrent validity.

AUTHOR CONTRIBUTION

Conceptualization: Oliveira ELS and Nogueira PC; **Methodology:** Oliveira ELS and Nogueira PC; **Investigation:** Oliveira ELS; **Writing – First version:** Oliveira ELS, Thum M; **Writing – Review and Editing:** Oliveira ELS; Thum M; Silva PSC; Nogueira PC; Santos VLCG; **Acquisition of Financing:** Nogueira PC and Santos VLCG; **Resources:** Santos VLCG and Nogueira PC; **Supervision:** Nogueira PC.

DATA AVAILABILITY STATEMENT

Data will be available upon request.

FUNDING

Not applicable.

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Not applicable.

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