

ORIGINAL ARTICLE

Evaluating self-reported pressure ulcer prevention measures in persons with spinal cord injury using the revised Skin Management Needs Assessment Checklist: reliability study

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Study design: Cross-cultural adaptation and reliability study.

Objective: To translate, evaluate the reliability and cross-culturally adapt the Skin Management Needs Assessment Checklist (SMnac), a questionnaire evaluating the knowledge on pressure ulcer (PU) prevention measures in persons with spinal cord injury (SCI).

Subjects: 138 persons with SCI, mean age 45.9 years, mean time since injury 94 months.

Material and method: The study was carried out in two stages. First, the questionnaire went through a forward-backward translation process and was cross-culturally adapted, according to a validated methodology for self-reported measures. Then, the test-retest reliability was evaluated on a population of persons with SCI

Results: The standardized back-translation and cross-cultural adaptation led to the revised Smack grid, with the addition of seven items representing an update of PU prevention measures. The reliability was excellent (intraclass correlation coefficient: 0.899).

Conclusion: The revised SMnac is an adaptation of the SMnac, including therapeutic education frameworks and the latest PU prevention practices. It appears to be a reliable tool for assessing the knowledge and benefits of PU prevention in persons with SCI. Further studies are needed to explore its validity and responsiveness to change.

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Introduction

Pressure ulcer (PU) is a common complication in persons with spinal cord injury (SCI). It affects around 20% of patients living at home;¹ and thus, is a major challenge for the public health care system both on a medical level (high rate of associated complications) as well as economical level (extended duration of hospital stays, multiple hospital stays).

Multiple risk factors were identified in persons with chronic SCI: social and demographical, neurological and also behavioral factors.^{2,3}

Several of these factors cannot benefit from a targeted prevention. However, physical medicine and rehabilitation (PM&R) professionals can and must have an impact on some of these factors, right from the initial acute phase, such as behavioral factors, by educating patients on skin lesion prevention.^{4,5}

One of the objectives of an initial PM&R hospital stay is to enable the patient to take charge of his/her own health by implementing proper measures for preventing potential skin damages at home.

As soon as an educational strategy is defined for persons with SCI, it is essential to have the necessary means to evaluate the impact of this strategy not only on patients' knowledge, but also on self-implemented prevention measures. Most studies in the literature were conducted for evaluating the impact of a standardized therapeutic

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education on PU recurrence, patients' knowledge in terms of preventive measures only came as a secondary assessment.^{6,7} The questionnaires used to evaluate patient's knowledge were designed within the framework of these studies and their metrological qualities are unknown.

The Skin management needs assessment checklist (SMnac), a self-administered questionnaire, is highly relevant because it was designed and focused on assessing patient's knowledge and self-reported prevention measures in terms of skin lesions.⁸ It includes 12 questions divided into three different categories: 'skin checks', 'preventing PUs' and 'preventing wounds'.

It corresponds to the skin chapter of the Needs Assessment Checklist,⁹ which is a self-administered questionnaire listing the PM&R objectives of persons with SCI. This questionnaire was validated in the English language.

The SMnac English language validation was conducted on 317 patients,⁸ and reported good internal consistency (Cronbach: 0.85), as well as a good responsiveness to change. The test-retest reproducibility for SMnac is 0.90. (see refs 9, 10)

The objectives of this study were first to translate, cross-culturally adapt in light of the latest PU prevention practices and secondly conduct a reproducibility study on the revised SMnac scale.

Materials and methods

This study was carried out in two stages. First, the SMnac was submitted to a forward-backward translation process and a cross-cultural adaptation. Then, the test-retest reliability was assessed in persons with SCI. The study protocol was approved by the Ethical Committee of Southern France (*Comité de Protection des Personnes Sud Méditerranée 3 Nîmes, France*).

Skin management needs assessment checklist

SMnac is derived from the Needs Assessment Checklist with nine areas to explore the PM&R indicators specific to persons with SCI. SMnac corresponds to the skin management area and aims at evaluating the self-reported prevention measures of persons with SCI as well as their knowledge regarding SCI-related skin disorders.

This self-administered questionnaire includes 12 questions divided into three categories: 'skin checks', 'preventing PU' and 'preventing wounds'. The 12th question relates to buying a mirror for skin checks, but it is not computed into the final score. Each item is scored from 0 to 3 (0 = completely dependent, never does to; 3 = completely independent, always does or instructs someone to). The total score is expressed as a percentage.

Forward-backward translation

The objective of this phase was to translate, as accurately as possible the English version of the SMnac into French. The translation methodology followed the good practices translation guidelines for self-reported measures.^{11,12} The back-translation technique is described below.

The translation was done by a professional translator, native French Speaker, with a university degree in medical and scientific English translations (Bénédicte Clement). It was recommended to do a literal-idiomatic translation—that is, keeping the true meaning and achieving the closest natural equivalent of each item—rather than word-for-word translation. A meeting was scheduled with the coordination committee in order to bring up problems encountered during the translation and resolve any disparities.

The backward translation had to be conducted by a native English speaker and professional translator (Teresa Sawyers). This step was essential to ensure that the meaning of each item was correlated to the original English version. Another meeting with the coordination committee was scheduled to bring up any unresolved issues.

The concordance assessment between the original SMnac version and the back-translated version was conducted by the British team who designed the original scale, headed by Paul Kennedy in the United Kingdom (six experts).

The concordance was evaluated item per item according to the methodology described by Sperber.¹³ Each expert rated each item according to two parameters: (1) Comparability of language: do the words or sentences match and (2) Similarity of interpretation: do the items have a similar meaning (even if the words are different). For each item, we calculated the mean of responses and came up with a number. To validate the translation, we need to have a comparability of language <3 or a similarity of interpretation <2.5. In case of disparity, the forward and backward translation process of the item need to be carried out again until reaching a definite agreement.

Cross-cultural adaptation

Acceptability and feasibility study of the pre-final version of the SMnac. The objective of this study was to evaluate the acceptability and feasibility of the forward-backward translated SMnac scale before its cross-cultural adaptation (pre-final version) on a population of persons with SCI. The patients were persons with SCI regardless of its etiology. Exclusion criteria were: cognitive or psychiatric disorders, unstable medical condition and also poor mastering of the French language.

The recruitment was done by the PM&R and Neurological Center PROPARGA (Centre Neurologique Mutualiste PROPARGA Montpellier, France). The evaluations were conducted by the main author (AG). After giving the patient information on the study's objectives, the examiner handed-out the SMnac's pre-final version. No guidelines were given to the patient besides the requirement to answer all questions. The questionnaire was collected back 1–2 h later and patients were invited to voice their comments and remarks during a semi-guided individual interview. First, patients spoke up freely before the examiner went through the main questions (objective of the scale, time spent completing the scale, the way items are described, scoring description and overall comments on the scale).

Content validity. Content validity refers to the extent to which a measure represents all facets of the categories to be

measured, and that each category is represented by an adequate number of items according to its relevance.

The scale was reviewed by three nationally recognized experts on persons with SCI and PUs (P-AJ, TA and DC), their goal was to adapt the scale to the latest prevention practices used in PM&R units.

This expertise was performed in two stages:

- First an individual meeting was set up with each expert. The meeting started with a presentation of the theoretical framework and objectives of the scale. Then the expert shared his/her remarks and comments on the revised scale: domains explored, critics of the items selected and categories defined, highlighting missing items in some pre-examined areas. Lastly, a summary of the meeting(s) with the previous expert(s) was presented.
- After these meetings, the coordination committee made changes to the SMnac and gave it back to the experts for final validation and approval (P-AJ, TA and DC).

Acceptability study of the SMnac revised version. The study's methodology was strictly similar to the first acceptability study.

Reliability study

The test-retest reproducibility was assessed on a sample of persons with SCI who met the same inclusion criteria defined for the acceptability study. The investigator gave the patients clear and precise information and collected their signed consent form.

The persons included in the study answered the questionnaire twice with a 4-day interval in between. During the first administration of the questionnaire, the items were listed at random in order to decrease the risk of memory biases.

Statistical analysis

To evaluate the correlation degree between the various scores at D1 and D4, the intraclass correlation coefficients (ICC) were calculated. The reproducibility was classified, according

to the Landis and Koch classification,¹⁴ as excellent ($0.8 < ICC \leq 1$), good ($0.6 < ICC \leq 0.8$), fair ($0.4 < ICC \leq 0.6$), poor ($0.2 < ICC \leq 0.4$), or bad ($0 < ICC \leq 0.2$).

To evaluate the correlation level of all questions between D1 and D4, the kappa coefficient agreement was calculated. The significance threshold is $P < 0.05$. Weighted kappa coefficient was calculated with a 95% confidence interval for ordinal modalities. For data analysis, we used the S.A.S. software version 9.1 and R (SAS Institute Inc., Cary, NC, USA).

Results

Translation/back-translation

During the first translation/back-translation cycle, the comparability of language analysis led to the validation of half the items (Table 1). The similarity of interpretation analysis did not validate any additional item. The discordant items were submitted to a second translation and back-translation cycle using the same modalities. All items were validated during the second cycle.

Cross cultural adaptation

Acceptability study for the pre-final SMnac version. A total of 19 patients were included in the study. Mean age 42 years (range: 16–74, s.d. = 18), 79% of them were men.

The qualitative analysis focused on the comments and remarks formulated by patients and the evaluator's observations during the individual meetings.

- The SMnac objective was well understood by patients. For 16 patients, the notion of PU prevention was mentioned. The other 3 patients extended this notion to skin disorders in general, 6 patients noted the notion of evaluating knowledge and self-reported prevention measures, and 2 patients reported the notion of autonomy in PU prevention.
- The questionnaire was reported as time-consuming by only one patient. This elderly patient, affected by a recent metastatic epidural spinal cord compression with associated

Table 1 Back-translation cycles. Values are mean scores. The item translation is validated if comparability of language mean score < 3 or similarity of interpretation mean score < 2.5

	Items	First back-translation cycle		Second back-translation cycle	
		Comparability of language	Similarity of interpretation	Comparability of language	Similarity of interpretation
Skin checks	1	1	1	—	—
	2	2	1	—	—
	3	1.66	1.83	—	—
	4	3.66	3.66	1.66	1
Preventing pressure ulcer	1	2.16	2.16	—	—
	2	2	1.83	—	—
	3	4.33	4.5	2.16	1.83
	4	4.16	4.16	2	1.66
Preventing wounds	1	1.66	1.5	—	—
	2	2	2	—	—
	3	3.83	4	2.16	1.66
	4	3.5	3.66	2.66	2.33

paraplegia believed that PU prevention was the sole responsibility of healthcare professionals.

- Regarding items' description, 12 patients did not report any miscomprehension issues. The remarks made by patients were mainly on two items, that each included two distinct questions with only one possible answer.
- Furthermore, three patients suggested including additional at-risk situations, according to their personal experience (sports practice, car driving and heaters for burns risks). A patient noted the lack of question on the choice or maintenance of specific PU prevention equipments (for example, mattress and wheelchair cushions).
- The scoring modalities raised more difficulties for patients as only five of them found them to be precise and clear. Their remarks were divided into four categories: the answers were not directly related to the question, but located at the top of the document, thus the patient had to go back and forth several times ($N=8$), the fact of having three possible answers for each scoring level was deemed as complex ($N=6$), no patient used the answer N/A, finally for some questions, the answer grid was inadequate as the question could only lead to a Yes/No answer ($N=4$).
- Most patients had a positive opinion of the questionnaire.
- Only three patients had a negative opinion of the questionnaire that could be explained by their very recent SCI (less than 1 month).

Content validity. In the g individual meetings, the experts suggested a change in the way the scoring system was laid out and a new wording for the answers of certain items. All experts agreed that the area 'preventing PUs' was under-represented in light of their clinical experiences in caring for persons with SCI and suggested adding seven more items. The additional items focused on detecting the early-onset of a PU by skin palpation, on evaluating the increased risk due to time spent in a wheelchair or certain sport practices, as well as life habits (smoking, nutrition), but also guidelines on how to react to a lingering redness of the skin, or checking PU prevention equipment.

Following the experts' recommendations, the Coordination Committee worked on a new version of the SMnac scale. Three experts validated separately the changes brought to this scale and came up with the revised SMnac scale (Annex 1).

Acceptability study of the revised version. A total of 15 patients agreed to be included in the study. In all, 3 had to be excluded for insufficient data. The mean age was 56 years, 67% were men.

The study showed a good acceptability of the revised SMnac by patients. The questions as well as the scoring system were evaluated as clearly laid-out. There was no misunderstanding of the questionnaire's objectives and the relevance was correctly identified for most persons. Patients did not report any comprehension or interpretation issues regarding the items and scoring system.

Reliability

Characteristics of the studied population. We analyzed the data from 138 persons with SCI. The mean age was 45.9 years

Table 2 Clinical and demographics characteristics of the persons with SCI included in the study ($N=138$)

Characteristics	Total ($N=138$)
Demographics	
Age (year)	45.9 ± 14.9 (E: 19–82)
Sex	
Men	103 (75)
Women	35 (25)
Weight (kg)	70.4 ± 14 (E: 37–114)
Height (m)	1.73 ± 0.09 (E: 150–197)
BMI (kg m^{-2})	23.9 ± 3.7
Lesion characteristics	
Age at the time of the injury (years)	38 ± 16 (E: 10–82)
Age of the injury (month)	94 ± 127 (E: 1–696)
ASIA Score	
A	83 (60)
B	16 (11.5)
C	15 (11)
D	14 (10)
Lesion level	
Cervical	49 (36)
Upper and lower back	89 (64)
Etiology	
Traumatic	112 (81)
Medical	26 (19)
Skin characteristics	
Braden (6–23)	15.8 ± 3 (9–23)
Pressure Ulcer Number	
0	91 (66)
1	35 (25)
2	7 (5)
3	4 (3)
Location	
Sacrum	23 (50)
Ischium	11 (24)
Heel	4 (9)
Trochanter	3 (6)
Others	5 (10)
Stage (NPUAP)	
1	6 (13)
2	11 (24)
3	17 (37)
4	13 (28)

Abbreviations: ASIA, American Spinal Injury Association; NPUAP, National Pressure Advisory Panel 2007; SCI, spinal cord injury.

The results are presented in Mean ± s.d. or N (%).

(range: 19–82, s.d. = 14.9), 75% were men. The main demographics and clinical characteristics of these patients are summed up in Table 2.

Global reproducibility. The ICC is 0.899 (CI 95%: 0.862; 0.927), thus validating a very good reproducibility according to the Landis and Koch classification (Table 3).

Table 3 Global reproducibility and reproducibility per center for the revised SMnac and its subscores

Reliability ICC (%)	N	Skin checks	Preventing pressure ulcers	Preventing skin insults	Total
Global	138	0.879 (0.836; 0.912)	0.872 (0.826; 0.907)	0.775 (0.699; 0.83)	0.899 (0.862; 0.927)
<i>Per center</i>					
Center 1	16	0.702 (0.351; 0.880)	0.801 (0.545; 0.92)	0.701 (0.348; 0.88)	0.857 (0.656; 0.945)
Center 2	24	0.896 (0.779; 0.953)	0.837 (0.665; 0.925)	0.677 (0.393; 0.843)	0.867 (0.722; 0.939)
Center 3	13	0.989 (0.966; 0.997)	0.984 (0.950; 0.995)	0.982 (0.949; 0.995)	0.989 (0.969; 0.996)
Center 4	25	0.936 (0.864; 0.971)	0.892 (0.775; 0.950)	0.626 (0.324; 0.813)	0.903 (0.797; 0.955)
Center 5	35	0.780 (0.611; 0.881)	0.848 (0.724; 0.919)	0.750 (0.563; 0.864)	0.864 (0.752; 0.928)
Center 6	25	0.882 (0.756; 0.945)	0.85 (0.704; 0.926)	0.806 (0.624; 0.905)	0.885 (0.768; 0.944)

Abbreviations: CI, confidence interval; ICC, intraclass correlation coefficients; SMnac, Skin Management Needs Assessment Checklist.

Table 4 Test—retest reliability of the items for the revised SMnac (weighted kappa coefficient)

SMnac categories	Items for each category										
	1	2	3	4	5	6	7	8	9	10	11
Skin checks	0.91	0.74	0.66	0.74	—	—	—	—	—	—	—
Preventing wounds	0.58	0.60	0.54	0.50	—	—	—	—	—	—	—
Preventing pressure ulcer	0.64	0.60	0.57	0.47	0.71	0.60	0.61	0.62	0.70	0.50	0.58

Abbreviation: SMnac, Skin Management Needs Assessment Checklist.

Reproducibility by subscore. The subscores reproducibility analysis showed a good reproducibility for all three subscores. The reproducibility by investigation center showed a good to very good reproducibility according to the centers. The global reproducibility standard variation per center is acceptable, ranging between 0.864 and 0.989.

If we look at the reproducibility analysis by subscore and by center, it appears that subscore 3 is the one with the largest reproducibility variation between the different centers (Center 4: 0.626; Center 5: 0.982).

Reproducibility analysis for each item. The reproducibility analysis of each item was computed with the weighted kappa coefficient. Only one item had a very good reproducibility, 11 items had a good reproducibility and 7 items had a moderate reproducibility (Table 4).

Discussion

The revised SMnac is a self-administered questionnaire aimed at persons with SCI. It is designed for evaluating their knowledge and is adapted to the latest prevention measure for PU prevention in persons with SCI.

Cross-cultural adaptation was the key element of this study. The guidelines regarding cross-cultural adaptations recommended to conduct an acceptability study on the translated questionnaire, among a sample group of patients.^{11,12} In our case, the acceptability study was deemed extremely useful, as it yielded several changes taken into account by the Coordination Committee and submitted to medical experts for content validity. Cross-cultural adaptations were made, the experts wanted to highlight the importance of the area 'preventing PUs' by adding seven

items, representing the prevention measures taught in France. Only two items of the original scale were modified and no item was discarded.

The global reproducibility of the SMnac is very good (ICC = 0.899 (0.862; 0.927)). It is similar to the reproducibility of the original SMnac version,⁹ implying that additional items included for the area 'preventing PUs' did not alter its metrological property.

The reproducibility per item varies greatly. This suggests that the scale's relevance lies in the global score and not in the item-per-item interpretation. This is often seen in the literature for questionnaires' validation.

The SMnac good reproducibility was a mandatory prerequisite for its validation. Further studies are needed to assess the validity and responsiveness to change and thus complete the validation of this questionnaire before it can be used in daily medical practices.

Study limits

This study had three potential limitations. First of all the subjects recruited for the reproducibility study were persons with a recent SCI or person re-hospitalized within a PM&R setting. There is a need for caution and maybe even further studies to extrapolate the results to persons with chronic SCI. Furthermore, in the acceptability studies of the pre-final version and the revised version, we did not quantify the time spent filling out the scale. Even though no patients made any comments, it would be justified to explore this notion, especially in persons with quadriplegia. Finally the reproducibility results per center unveiled that Center 4 had an excellent reproducibility in all the studied areas. As this Center was pretty reluctant to conduct this study, we came to the conclusion that these results were suspicious. Even

though the overall reproducibility of the questionnaire is very good without Center 4, we decided to exclude this center from the other validation stages.

To conclude, the revised SMnac is a self-administered questionnaire for evaluating the knowledge of persons with SCI and their self-implemented prevention measures. This scale was updated to include the latest clinical practices, including PU therapeutic educational frameworks. Its global reproducibility is very good, encouraging us look forward to validating the scale through further studies on validity and responsiveness to change.

Conflict of interest

The authors declare no conflict of interest.

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