

BMJ Open Spanish adaptation and validation of the Pain Assessment Scale in Advanced Dementia (PAINAD) in patients with dementia and impaired verbal communication: cross-sectional study

Vanesa Cantón-Habas,¹ María del Pilar Carrera-González ^{1,2},
María Teresa Moreno-Casbas,^{3,4} Manuel Rich-Ruiz ^{1,3,4}

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For numbered affiliations see end of article.

Correspondence to

Dr María del Pilar Carrera-González; pcarrera@uco.es

ABSTRACT

Objectives The aim of this study was to adapt and validate the Pain Assessment in Advanced Dementia (PAINAD) scale in Spanish.

Design Cross-sectional observational study.

Setting Two health districts of Andalusian provinces, located in the south of Spain, through the Andalusian network of Primary Healthcare centres and four institutions dedicated to the care of patients with dementia.

Participants A total of 100 older people, with a medical diagnosis of dementia and a score on the Global Deterioration Scale between 5 and 7 were assessed using the PAINAD scale.

Primary and secondary outcome

measures Psychometric properties including content validity, construct validity and reliability of the scale have been tested.

Results The overall Item Content Validity Index was excellent (0.95). Regarding construct validity, it was confirmed that a lower use of analgesics implied a lower score on the PAINAD scale ($p < 0.05$). The internal consistency of the scale was 0.76 and it increases to 0.81 if we remove the breathing item. Furthermore, the intraclass correlation coefficient (ICC) used to assess interobserver reliability was 0.94, whereas the ICC used to assess temporary stability was 0.55.

Conclusions The Spanish version of the PAINAD scale is a valid tool to assess pain in patients with dementia and inability to communicate verbally.

INTRODUCTION

Pain is an unresolved problem in older people, especially in those with cognitive impairment.¹ It is estimated that 50% of older people and 80%–85% of older people with dementia suffer pain as a result of suffering various chronic conditions.^{2–4} In addition, the prescription of analgesics is significantly lower in older people with dementia than among those with preserved cognitive abilities.^{5,6} This difference could be explained by the fact that pain assessment in people with

Strengths and limitations of this study

- Despite the previous existence of a Spanish version of the Pain Assessment in Advanced Dementia (PAINAD) scale, the validation and cultural adaptation process began with a translation/retro-translation of the original scale, guaranteeing the content of the scale.
- The PAINAD scale was completed by three researchers previously trained in its use to assess pain.
- Special attention was paid to the homogeneity of external conditions during the pain assessment process using the PAINAD scale.
- The study subjects were selected by consecutive sampling as there was no prior list of subjects meeting the inclusion criteria for the study, and this could interfere with the selection of participants.
- The time between test–retest, which happened 30 days apart, may have influenced the results achieved.

advanced dementia is clearly hampered by both loss of verbal communication ability and impaired perception and identification of painful experiences.^{2,7}

In this sense, self-reports of the person on pain are considered the gold standard due to their reliability discerning the presence and severity of pain. However, the usefulness of these self-reports is stage-dependent, particularly limited by impaired verbal communication in people with advanced dementia.^{8,9} Therefore, in people with this condition and inability to communicate effectively verbally, behavioural observation-based pain assessment tools become the best choice for assessing pain.^{10–12}

This alternative to verbal assessment of pain in people with advanced dementia has promoted the development of more than 24

tools with this same objective, which have been adapted and validated in other languages.^{5 13–17} Specifically, the most recommended tools for pain assessment in this population are the Abbey Pain scale,¹⁸ Doloplus 2,¹⁹ the Assessment of Pain in Elders with Dementia scale,²⁰ the Non-communicative Patient's Pain Assessment Instrument,²¹ the Checklist of Non-verbal Pain Indicators,²² the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC)²³ and the Pain Assessment in Advanced Dementia (PAINAD) scale.²⁴

However, previous studies point to the PACSLAC scale as the tool of choice for research studies, and the PAINAD scale as the ideal tool for assessing pain in clinical practice.^{25–28} Therefore, the PAINAD scale has been culturally adapted and validated for the assessment of pain in people with advanced dementia in different countries, such as Singapore,²⁹ the Netherlands,³⁰ Italy,³¹ China,³² the UK,³³ the USA,³⁴ Brazil,³⁵ Turkey³⁶ and Germany.³⁷ However, its previous validation in Spanish has been superficial due to limitations of sample size and sample origin,^{38 39} and further validation studies with larger samples are therefore required.⁴⁰

Objective

The main objective of this study is to adapt and validate the PAINAD scale in the Spanish language. The specific objectives will also be to evaluate the content and construct validity and the internal consistency of the Spanish version of the scale.

METHODS

Design

Cross-sectional observational study conducted in two health districts of Andalusian provinces, located in the south of Spain, through the Andalusian network of Primary Healthcare centres and four institutions dedicated to the care of patients with dementia. This study began in May 2018 and finished in May 2020.

Participants and selection criteria

The study participants were patients with dementia or Alzheimer's disease (AD) meeting the following inclusion criteria:

- ▶ Age ≥ 65 years.
- ▶ Being diagnosed with dementia or AD with a Global Deterioration Scale (GDS) score between 5 and 7.⁴¹ Patients received diagnosis of dementia if they met Diagnostic and Statistical Manual of Mental Disorders—V clinical criteria and received a diagnosis of probable or possible AD according to the National Institute of Neurological and Communicative Disorders and Stroke/Alzheimer's Disease and Related Disorders Association criteria.
- ▶ Being unable to communicate verbally.
- ▶ Having received healthcare at the community level for at least 3 months because of a diagnosis of dementia. In the case of the institution dedicated to the care of

patients with dementia, the patients included were those who had been using this service for at least 3 months.

- ▶ Having a relative or legal representative that could sign the informed consent for the participation of the patient in the study.

The recruitment of the patients with dementia was conducted consecutively by the interventional nurses among the subjects under their care in their healthcare institution. In this sense, all patients meeting the inclusion criteria were included in the study.

Regarding the sample size, between 5 and 20 subjects per item are needed to validate scales, or, at least, 100 subjects in scales with less than 10 items. Therefore, the number of subjects needed for validation of the PAINAD scale is 100 subjects.⁴²

Measures

For the description of the sample, the following sociodemographic and clinical variables were collected: sex, age, marital status, medical diagnosis of dementia, GDS score, Barthel Index score and use of analgesics.

Likewise, pain in people with advanced dementia and impaired verbal communication was evaluated at rest using the PAINAD scale by three researchers previously trained in its use and specific interpretation of each item. This scale is composed of five items: breathing, negative vocalisation, facial expression, body language and consolability. Each of these dimensions was evaluated by the observer using a Likert-type scale (0–2) based on the pain severity. The total score will result from the sum of the values obtained in the five items, ranging between 0 and 10 points.

In general, clinical and sociodemographic variables were collected from the patient's medical history. However, the scales (GDS and Barthel Index) were administered by the research team at the time of data collection or, if collected from the medical record, were not more than 3 months old.

Adaptation and validation of the PAINAD scale

Linguistic adaptation and validation

The linguistic validation process was performed using the forward–backward translation method. However, the existence of the Spanish version published by García-Soler *et al*³⁸ allowed us to start from this version to skip the translation of the tool from English to Spanish. Therefore, two translators, whose native language was English, with experience in health sciences, and specifically in nursing, were identified to translate the García-Soler *et al* version independently³⁸ into English. The two versions of the scale resulting from this process were unified to obtain a single back-translation that was compared with the original²⁴ to check the level of discrepancy. If 5% or more of discrepancy in the use of words with the same meaning was found, the linguistic validation process would be restarted.

Content validity

The translated version of the tool was submitted to eight independent experts with the following selection criteria: bilingual nurses or other health professionals, with clinical experience in caring for people with AD and other dementias, familiar with the research process and with regular access to email. However, two additional backup experts were identified to replace possible losses.

Once the experts were identified, they were formally invited to participate in the project via an email, which contained a letter requesting their participation and a document containing the two versions of the PAINAD scale (the original in English and the Spanish version).

The participation of each expert consisted in the determination of whether each item on the scale was relevant to the study population and whether the wording was appropriate. For this purpose, they rated the items with an ordinal scale from 1 (irrelevant) to 4 (highly relevant). Each expert was allowed 10 days to complete the evaluation form.

Construct validity

The hypothesis to assess the validity of the PAINAD scale stated that a higher score on the PAINAD scale is associated with a lower degree of dependence for basic day-to-day activities according to the Barthel Index and with a lower use of analgesics.

Reliability

Reliability was assessed through analysis of internal consistency, interobserver variability and intraobserver temporary stability (test–retest). A second pain assessment was performed at 30 days to assess stability over time.

Statistical analysis

The median, mean, SD, maximum and minimum of the quantitative variables and the absolute and relative frequencies of the categorical variables were calculated to describe the general characteristics of the patients.

The Content Validity Index was calculated to evaluate the content validity of the PAINAD scale. For this purpose, it was necessary to calculate:

- ▶ The number of agreements, understanding ‘agreement’ as the number of experts who gave the item a score of 3 or 4 in the evaluation of relevance.
- ▶ The level of the validity of the item (Item Content Validity Index (I-CVI)), considering scores greater than or equal to 0.78 as acceptable^{43 44} ($I - CVI = \frac{\text{number of raters scoring an item with a 3 or 4}}{\text{total experts}}$).
- ▶ The probability of random concordance (p_c), having to obtain values the smaller the better
$$p_c = \left[\frac{[N]}{[A!(N-A)!]} \right] \times 0.5^N.$$
- ▶ The modified kappa coefficient. The criteria applied was the one defined by Fleiss (1981), who established four ratings: excellent (≥ 0.74), good (0.60–0.73), moderate (0.40–0.59) and poor (≤ 0.39)⁴⁴ $k = \frac{I - CVI - p_c}{1 - p_c}$.

- ▶ The average of all I-CVI scores. A minimum score of 0.80 was accepted as adequate validity, while ≥ 0.90 represented a high validity.⁴⁵

Regarding construct validity, the Pearson or Spearman’s Rho correlation indexes were calculated according to the distribution of the data, seeking the association between the Barthel Index score or the number of analgesics per day and the PAINAD score.

The statistical method used to check internal consistency was Cronbach’s alpha coefficient, considering alpha values above 0.7 as good internal consistency. In addition, the confirmatory factor analysis (CFA) was used to assess the goodness-of-fit of the factor structure. The intraclass correlation coefficient (ICC) was used to assess variability between observers and temporary stability.

IBM SPSS Statistics 22.0 (SPSS/IBM), Epidat V.4.1 (Department of Sanidad, Xunta de Galicia, Galicia, Spain) and the Lavaan R package software (V.3.5.0) have been used for the statistical analysis of the data. The level of statistical significance was set at an alpha error below 5% for all the statistical tests and a CI of 95%.

Ethical aspects

The principles of the Declaration of Helsinki and the Belmont report on ethical precepts for biomedical were followed thoroughly. In this sense, the relatives, or legal representatives of the candidates for entry into the study were informed through a Patient Information Sheet and the written informed consents were obtained. Subject anonymity and data confidentiality were always guaranteed. In addition, the study has the authorisation of all participating centres and the permission of the Ethics Committee for Research of Andalusia (Acta n° 271, ref. 3672, approved on 5 December 2017).

Patient and public involvement

The research question for this study was developed based on the available scientific literature on the subject. Therefore, patients and public were not involved in the design of the study.

RESULTS

Sample characteristics

A total of 100 patients with dementia or AD constituted the final study sample. Their sociodemographic and clinical characteristics are shown in [table 1](#).

PAINAD validation

Linguistic adaptation and validation

The back-translation of the García-Soler tool³⁸ showed a discrepancy rate of 7%, so the process of linguistic validation of the tool had to be restarted. The last translation did not exceed 5% discrepancy, which allowed the Spanish version to be considered appropriate for its application.

Content validity

The overall content validity of the Spanish from Spain version of the PAINAD scale (S-CVI) was 0.95, with a

Table 1 Characteristics of the study sample

Variable		
Age (years)	Mean (SD)	83.80 (7.82)
	Min–Max	65–95
	M _e	83.80
Sex	Male	78 (78%)
	Female	22 (22%)
Marital status	Single	9 (9%)
	Married	27 (27%)
	Separated-divorced	2 (2%)
	Widowed	62 (62%)
Medical diagnosis	AD	76 (76%)
	Vascular dementia	8 (8%)
	Primary degenerative dementia	3 (3%)
	Mixed dementia	13 (13%)
GDS	GDS 5	13 (13%)
	GDS 6	42 (42%)
	GDS 7	45 (45%)
Barthel Index score	Mean (SD)	18.55 (21.30)
	Min–Max	0–80
	M _e	18.55
Use of analgesics	Yes	44 (44%)
	No	56 (56%)
Analgesics per day (number)	Mean (SD)	0.73 (1.09)
	Min–Max	0–6
	M _e	0

.AD, Alzheimer's disease; GDS, Global Deterioration Scale; Max, maximum; M_e, mean; Min, minimum.

minimum I-CVI of 0.875 and a maximum of 1.00. The results of the content validity indicators for each of the dimensions constituting the PAINAD scale are shown in [table 2](#).

Table 2 Results of the content validity of the Spanish version of the PAINAD scale

	I-CVI	p _e	k	Rating*
Breathing	0.88	0.031	0.87	Excellent
Negative vocalisation	0.88	0.031	0.87	Excellent
Facial expression	1.00	0.004	1.00	Excellent
Body language	1.00	0.004	1.00	Excellent
Consolability	1.00	0.004	1.00	Excellent

*Evaluation criteria of kappa according to Fleiss.⁴⁵

I-CVI, Item Content Validity Index; k, modified kappa coefficient obtained by designing the relevant proportion of agreements; ; PAINAD, Pain Assessment in Advanced Dementia; p_e, probability of random agreement.

Construct validity

The construct validity of the PAINAD scale was evaluated assuming that a lower level of pain in this tool was associated with a lower degree of dependence for the basic activities of daily life according to the Barthel Index and a lower use of analgesic drugs. However, the results indicate that according to Pearson's correlation coefficient there is no association between the Barthel Index score and the PAINAD score, regardless of observer 1 (p=0.45), observer 2 (p=0.66) or observer 3 (p=0.95).

However, regarding the correlation between the PAINAD score and the number of analgesics used by patients with advanced dementia, the latter was significantly lower in those patients with a lower PAINAD score. Specifically, according to observer 1, p=0.002 (95% CI: 0.044 to 0.523), for observer 2, p<0.001 (95% CI: 0.067 to 0.649) and for observer 3, p<0.001 (95% CI: 0.094 to 0.605).

Reliability analysis

Internal consistency

The overall Cronbach's alpha coefficient value was 0.76. However, if we remove the breathing dimension from the analysis since it is a constant, the overall value of Cronbach's alpha increases to 0.81. In the same way, the overall value of Cronbach's alpha coefficient was 0.81 in the retest, increasing to 0.85 if the breathing dimension is removed. [Table 3](#) shows the internal consistency results of both the test and retest for each of the three observers, both including the breathing dimension of the scale and after its removal.

Furthermore, [table 4](#) shows the internal consistency results for each item of the PAINAD scale. Breathing was not included because its values were a constant.

Finally, the CFA was used to assess the goodness-of-fit of the factor structure of five items for median of the observations. We obtained a good fit in terms of the comparative fit index which was 0.947 (breathing was not used).

Inter-observer variability

To evaluate the interobserver agreement of the Spanish version of PAINAD scale, the overall ICC value was 0.94 (95% CI: 0.92 to 0.96). In this regard, the ICC was 0.91 (95% CI: 0.88 to 0.93) for the negative vocalisation item, 0.84 (95% CI: 0.79 to 0.89) for the facial expression, 0.78 (95% CI: 0.70 to 0.83) for the body language and 0.61 (95% CI: 0.50 to 0.70) for consolability.

Temporary stability

The overall ICC between the pre-test and post-test scores was 0.55 (95% CI: 0.32 to 0.70), p<0.001. In this case, the ICC value was 0.50 (95% CI: 0.26 to 0.67), p<0.001 for the negative vocalisation, 0.63 (95% CI: 0.44 to 0.75), p<0.001 for facial expression, 0.52 (95% CI: 0.30 to 0.68), p<0.001 for body language and 0.51 (95% CI: 0.26 to 0.57) for consolability.

Table 3 Internal consistency of the scale according to the observer. Cronbach's alpha values

	Cronbach's alpha	95% CI	Cronbach's alpha if the breathing dimension has been deleted	95% CI
<i>Test</i>				
Observer 1	0.803	0.779 to 0.874	0.857	0.815 to 0.894
Observer 2	0.780	0.715 to 0.837	0.831	0.781 to 0.875
Observer 3	0.710	0.624 to 0.785	0.743	0.667 to 0.810
<i>Retest*</i>				
Observer 1	0.795	0.732 to 0.849	0.845	0.798 to 0.886
Observer 2	0.825	0.772 to 0.8171	0.880	0.843 to 0.912
Observer 3	0.810	0.752 to 0.860	0.832	0.781 to 0.877

*The sample consisted of 95 patients due to the death of some of the study subjects.

DISCUSSION

The results of the study show that the Spanish version of the PAINAD scale, according to its psychometric properties and in line with previous studies,³⁹ is a valid observational tool for assessing pain in people with dementia and impaired verbal communication.

The Spanish version of the PAINAD scale, based on the results of the present study, shows an excellent content validity. In this sense, if we compare the Spanish version with the Turkish one, the mean value of the I-CVI in the Turkish version was 0.84, and given that the value of the Spanish version was 0.95, we can affirm that the Spanish version is better.³⁶

Regarding the association between the PAINAD scale score and the degree of dependence for basic activities of daily living measured through the Barthel Index (used to evaluate construct validity), the results have not shown that those subjects with advanced dementia and a lower level of pain also have a lower degree of dependence. However, this could be explained by the degree of dependence of the subjects constituting the sample, since 93% (n=93) had dependence classified as severe or total, according to the Barthel Index. Specifically, 30% (n=30) had severe dependence and 63% (n=63) had total dependence on basic activities of daily life. In contrast, the expected results for lower analgesic use among those with advanced dementia who had lower pain levels have been verified, according to the PAINAD scale.

The found reliability was similar to the values obtained in the validation of other languages, such as the Italian version of this tool, with an internal consistency of

0.74³¹; the Brazilian version, whose value of the Cronbach's alpha was 0.65³⁵ or the German version, which has the best results, since internal consistency reached 0.85.³⁷

However, the results of the Spanish version of the PAINAD scale are even better if we remove the breathing dimension (Cronbach's alpha of 0.81 and 0.85). Something similar occurs in the García-Soler version, with a Cronbach's alpha value ranging from 0.47 to 0.83 (with a mean of 0.70), which was higher if the breathing item was removed³⁸; or the Chinese version of the scale, which initially ranged from 0.55 (during assisted transfer) to 0.66 and increased to 0.71 if the breathing dimension was removed from the analysis.³²

Regarding the degree of agreement among observers, the ICC values of this version (0.94) are higher than those found by the Chinese version (0.84)³² and the Turkish version (0.81).³⁶

Finally, regarding temporary stability, the findings of this study have shown a moderate reliability of the PAINAD scale in its Spanish version, since the ICC is 0.55. This has been lower than other versions, since the ICC of the Chinese version ranges from 0.80 to 0.86,³² the ICC of the Turkish version is 0.81,³⁶ the ICC of the German version is 0.80³⁷ and the ICC of the Italian version is 0.88.³¹ This difference could be explained because the retest was performed after a shorter time interval^{31 32} in other studies, such as in the German version,³⁷ which performed both the test and the retest on the same day. However, despite choosing a longer period of time for our study, we ensured that no relevant clinical variation

Table 4 Internal consistency results for each item. Cronbach's alpha values

	Corrected total element correlation	Cronbach's alpha if the element has been deleted	95% CI
Negative vocalisation	0.83	0.73	0.65 to 0.80
Facial expression	0.70	0.77	0.70 to 0.83
Body language	0.70	0.78	0.72 to 0.84
Consolability	0.71	0.76	0.69 to 0.82

had occurred during those 30 days that could have interfered with the measurement.

Strengths and limitations

Before the validation step, the PAINAD scale was translated and backtranslated using a rigorous methodology despite the existence of a previous version in Spanish, which is a strength of our study. In addition, the PAINAD scale was filled in by three researchers who had previously received training in its use to assess pain in patient with advanced dementia and inability to communicate. Furthermore, external conditions were controlled as much as possible during the data collection process to minimise potential interference with the scale validation process.

However, there are also some limitations to this study. The use of consecutive sampling may have influenced the selection of subjects. However, there was no prior list of patients meeting the inclusion criteria, or even an estimate of the total number of patients with these characteristics. On the other hand, it should be noted that the test–retest is limited by the time elapsed between the two observations. However, the pre-existing scientific literature had used different temporalities to assess this psychometric property (reliability), so the results of the present study in this respect are adequate.

Implications for clinical practice and research

The PAINAD scale, according to its psychometric properties as well as its simplicity, presents itself as a promising instrument to combat both underdiagnosis and undertreatment of pain in patients with dementia and communication disability. However, it is important to take into consideration the need for health professionals who will be using the PAINAD scale to have adequate and specific training in its use.

Further studies are needed to identify the level of satisfaction of health professionals with its daily use in the care setting; to find out the limitations and difficulties of the inclusion of the scale in the care of patients with advanced dementia; as well as to determine the impact of its use in pain assessment.

CONCLUSIONS

The Spanish adaptation of the PAINAD scale seems to be a reliable and valid tool to evaluate pain in older people with advanced dementia and unable to communicate effectively verbally. In this regard, the PAINAD has shown an excellent content validity; an adequate construct validity for the studied phenomenon according to the correlation between the PAINAD score and the use of analgesics. In addition, the PAINAD scale has shown a high reliability, with an excellent internal consistency at the overall level both at the initial visit and at the retest, increasing if the breathing dimension is removed; a moderate temporary stability and an excellent general intraobserver reliability.

Author affiliations

¹Instituto Maimónides de Investigación Biomédica de Córdoba (IMIBIC), Universidad de Córdoba (UCO), Hospital Universitario Reina Sofía (HURS), Córdoba, Spain

²Experimental and Clinical Physiopathology Research Group, Department of Health Sciences, University of Jaen Faculty of Experimental Sciences, Jaen, Spain

³Ciber Fragility and Healthy Aging (CIBERFES), Madrid, Spain

⁴Instituto de Salud Carlos III, Nursing and Healthcare Research Unit (Investén-isciii), Madrid, Spain

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Contributors VC-H, MdPC-G and MR-R conceptualised the project and conceived the study design. VC-H and MdPC performed the data collection. VC-H analysed the data. VC-H drafted the manuscript. MdPC-G, MTM-C and MR-R reviewed and edited the draft manuscript. All authors read and approved the final document.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval The study was conducted following the ethical principles of the Helsinki Declaration. In addition, both the design and the development of the work meet the standards of good clinical practice (CPMP/ICH/135/95, July 2002, European Medicines Agency). The study was evaluated by a peer-review process and funded by a grant awarded under the call for proposals in Biomedical and Health Sciences R+D+I of the Regional Government of Andalusia (22 December 2017). This study was approved by the Research Ethics Committee of Córdoba, Health Department (Act No. 271, ref. 3672).

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Data availability statement All data relevant to the study are included in the article. Extra data are available upon reasonable request.

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ORCID iDs

María del Pilar Carrera-González <http://orcid.org/0000-0001-6575-8240>

Manuel Rich-Ruiz <http://orcid.org/0000-0003-3317-267X>

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