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A comprehensive study of psychometric properties of the Edmonton Symptom Assessment System (ESAS) in Spanish advanced cancer patients

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ABSTRACT

Background: The Edmonton Symptom Assessment System (ESAS) is developed for daily symptom assessment. Validation studies tested a variety of languages and patients. The purpose was to carry out a comprehensive examination of the psychometric properties of the ESAS through validation of the version in Spanish advanced cancer patients.
Method: A reverse translation method was used to translate the ESAS. Previous studies find appropriate Spanish terms to explore, with verbal scales, fatigue, depression and anxiety. Psychometric aspects evaluated were reliability, validity, responsiveness and utility.
Results: 171 advanced cancer patients participated. Internal consistency with Cronbach's Alpha was 0.75. In test–retest (0–6 h), Spearma's correlation was between 0.65 and 0.94. Factor analysis found 3 central domains: 'soft' and 'hard physical' and 'emotional'. Concurrent validity with the Rotterdam Symptom Check List (RSCL) found good correlation in physical symptoms (Kappa until 0.66) but weak correlation in emotional symptoms (Kappa 0.35). Discriminant validity (Spearman) found significant differences ($p < 0.001$) classifying by Karnofsky. ESAS discriminate between inpatients and outpatients (Mann–Whitney, $p < 0.001$). Responsiveness was tested with ESAS at 0–48 h (Wilcoxon test, $p < 0.05$). Average time to complete the instrument was 5.5 min.
Conclusion: ESAS is a valid, reliable, responsive and feasible instrument with adequate psychometric properties when tested on Spanish advanced cancer patients.
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1. Introduction

Systematic symptom assessments are useful to detect problems not easily identified in routine clinical care.[1] However, a significant challenge to obtaining evidence-based palliative care is the provision of culturally-adapted instruments that are validated in different languages and settings.[2]

There are several validated tools available for the assessment of symptoms in patients with cancer in both the early and advanced stages of the disease.[3] However, some of these tools are lengthy and, therefore, may be time consuming for both patients and health professionals. Some of the tools are developed only for cancer patients who are participating in clinical trials.[4] Tools used in palliative care settings should

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be easy to complete and to interpret[5] and would have to help in identifying cancer patient's most bothersome issues.[6] Furthermore, they should allow researchers to collect data for prospective studies, facilitating further research in palliative care.[7] Identify Cancer Patients' Most Bothersome Issues?

The original Edmonton Symptom Assessment System (ESAS) consists of ten visual analogue scales (VAS) exploring frequent symptoms in palliative care patients. The ESAS provides a quick and simple numerical assessment of the most common symptoms with a graphic display that facilitates interpretation and comparison over time. It was developed in 1991 to evaluate the intensity of the most frequent physical and psychological symptoms in cancer patients receiving palliative care, and was rapidly adopted by many cancer and palliative care programs.[8] The current version proposed by Bruera et al.[9] includes a new item entitled 'difficulty sleeping' and has amended the visual analogue scales for numerical rating purposes.

There have been independent validations of this tool in palliative care and cancer patients by a number of different authors and in a variety of different languages: for example, in English,[10–15] Italian[16] French[17], German[18] and Thai.[19] Chang et al. carried out a wide study of validation of the ESAS assessing four psychometric aspects; Two recent reviews on ESAS studies have found limited psychometric evidence that supports the need for further validation studies.[20,21] A more comprehensive validation is required since daily clinical decisions are being made about patient care on the basis of the ESAS, and the results of the tool are also used for clinical research and quality evaluation of clinical programs. The purpose of this study was to carry out a comprehensive examination of the psychometric properties of the ESAS through validation of the version in Spanish advanced cancer patients.

2. Methods

2.1. Translation and cultural adaptation

A reverse translation method was used by bilingual translators to translate the ESAS into Spanish.[22] This method is most commonly recommended by experts when cross-cultural studies are undertaken and includes several steps: translation into the target language by bilingual translators; correction by experts; back-translation and comparison of the translated version with the original version for semantic equivalence; and finally, agreement between a group of experts on the final version.[23,24]

Five bilingual Spanish palliative care professionals who possessed experience using the ESAS translated the English version into Spanish. Four evaluators graded each term for clarity, cultural appropriateness, and common language on a scale from 0 to 10; 0 demonstrated an absence of clarity, cultural appropriateness and common language, whilst 10 demonstrated maximum compliance. A committee of palliative care professionals selected the translated phrases with the highest scores. This version was used in a pilot study with 20 patients with advanced cancer, comprising of both inpatients and outpatients. The evaluating committee reviewed the comments made by the patients and then agreed on a second Spanish version of the survey. This version was then translated back into English by two bilingual translators. Four reviewers evaluated these versions compared to the original version in English. Using the reviewers' scores, the committee produced a third version of the survey, which was tested in a further study on five patients with cancer. After the final pilot study, patients' remarks were taken into account and the committee presented proposals for a Spanish version of the ESAS.

2.2. Participants

The validation study was performed in the Oncology and Haematology Departments at the University of Navarra Hospital, Pamplona, Spain, a reference tertiary hospital comprising mainly of Spanish and Portuguese cancer patients. Data were gathered between January and March 2008; inclusion criteria was advanced on cancer patients (both inpatient and outpatient), who were over 18 years of age, and possessed normal cognitive function based on the clinical impression of a researcher with palliative care experience. A total of 172 patients were approached, with only one patient declining to participate because of fatigue.

The study was approved by the Ethics Committee on Clinical Research (CEIC) at the University of Navarra Hospital (Spain). Written informed consent was obtained from the patients prior to their participation in the study, and authorisation to utilise the ESAS was received from the original author of the tool.

The following information on the patient's history was collected: general details (age, sex, level of education), clinical details (primary tumour and prognosis), Karnofsky Performance Status, type of oncological treatment (chemotherapy, radiotherapy, etc.) and goal (curative or palliative), place of residence and hospital status (inpatient or outpatient).

2.3. Sample size

To determine the sample size, a reference size comparable to other ESAS validation studies was utilised, ranging from 34[25] to 241[16]. The recommendations of statistical experts for each psychometric property were also taken into account. For example, in relation to studies on reliability and validity, the most suitable sample size is estimated to be between three and twenty times the number of variables in the survey[26]; this equates to between 30 and 200 subjects for the ESAS. In addition, factor analysis could require a larger sample size; a recommended sample size for test–retest reliability is 50 subjects.[27,28] To study concurrent validity and sensitivity, it was estimated that a minimum sample size of 39 patients would be required (for a standard deviation of 3.2 based on this study; in previous studies of similar populations with a statistical significant difference of 2/10 with alpha error of 5%, two tailed, on beta error of 20%).

Internal consistency and discriminant validity with 171 patients was studied; in addition, a subgroup of 146 patients took part in the test–retest reliability, another subgroup of 90 patients completed the RSCL, and a further subgroup of 45 patients undertook the responsiveness test–retest 48 h later. A subsample of 40 patients completed the patient perception survey.

2.4. Instruments

The Edmonton Symptom Assessment System (ESAS) has eleven numerical rating scales which explore frequent symptoms in palliative care patients. For this study of validation, we have chosen the latest English version of the tool that was proposed by the original author of the ESAS in 2002.[8] The symptoms included are: pain; fatigue; nausea; depression; anxiety; drowsiness; shortness of breath; appetite; difficulty in sleeping; and feeling of well-being. A blank scale is included for additional symptoms. The severity of each symptom is rated from 0 to 10 (0 = absence of symptom, 10 = worst possible intensity). Each numerical scale is interpreted independently from the other scales, although it is also possible to calculate a total symptom distress score (SDS) from the sum total of all the symptoms. The author recommended self-administration of the tool whenever possible; alternatively, a professional can help the patient to complete it. In our study, ESAS was completed with the assistance of the researcher nurse as most of the patients involved had not completed the ESAS before.

The Rotterdam Symptom Check List (RSCL)[43] consists of 39 items (Likert scale categories of frequency) that are grouped into four domains: quality of life; daily activities; psychological symptoms; and physical symptoms. It is usually self-administered, but can also be administered by a healthcare professional. It is validated in Spanish for evaluation of symptoms in cancer patients.[4]

The Karnofsky Performance Status (KPS) Karnofsky and Burchenal[29] combines information on the patient's ability to function, ability to work, the severity of symptoms, and the need for care. The KPS consists of eleven categories with scores divided into deciles ranging from 100 (asymptomatic, normal function) to zero (death). In this study, the researcher nurse completed the KPS.

Questionnaire on the patient's perception of the ESAS. In order to fully explore the patient's viewpoint, a survey was carried out using nine items from a previous study done by Watanabe et al.[14]; a number of additional closed questions explored whether patients preferred to complete their first ESAS alone or with the assistance of a nurse.

Clinical and demographic data, the KPS, and symptom intensity within the ESAS were collected on the first day of the study. Additionally, a sub-sample of patients completed RSCL on the same day. Approximately 4–6 h later, another sub-sample repeated the ESAS for the retest. In order to check responsiveness, a further sub-sample repeated the ESAS 48 h later. The time frame used to assess symptoms within both the ESAS and the RSCL was current. The survey on patient perception was done after the completion of the ESAS in the same interview.

2.5. Psychometric property analysis

Reliability: The internal *consistency* of the ESAS was measured by calculating the Cronbach's Alpha. It was also explored using Spearman's correlation between the sum of specific items (pain, fatigue, nausea, depression, anxiety, drowsiness, shortness of breath, appetite, difficulty in sleeping) within the ESAS, and the item 'feeling of wellbeing'; it was anticipated that there would be correlation between these items. *Test–retest* was measured in an interval from 0 to 4–6 h; this was a period in which significant changes in symptom severity were not expected to occur. The correlation between the two points in time was assessed using the Spearman's correlation coefficient and Lin's Concordance test, corresponding to ordinal qualitative variables.

Validity was examined by *concurrent and discriminant validity*. *Concurrent validity* was evaluated between the ESAS and the RSCL. In order to compare the two measures the ESAS scores (from 0 to 10) were recoded on a Likert scale ranging from 1 to 4.[30] The concordance between the two surveys was measured by Weighted Kappa. *Discriminant validity*, which assesses the ability to detect differences between groups, was evaluated by testing the difference of the ESAS score between patients with different functional states according to Karfnosky's Performance Status. This was measured using Spearman's correlation coefficient. Differences between inpatients and outpatients were also evaluated by the Mann–Whitney U test.

Factor Analysis was carried out to reduce the original items of the ESAS to fewer underlying dimensions in order to generate opportunities for further analysis. The factors were rotated by means of promax oblique rotation. Orthogonal methods were not utilised because it was expected that the items on the survey would generate interrelated factors.[31] Factor analysis is normally undertaken using Pearson's correlation matrix, but given that the variables in the study did not follow a normal distribution and are ordinal values, Spearman's correlation matrix was chosen instead. Other studies with ESAS have also used non-parametric tests.[32]

Responsiveness, which evaluates the ability of an instrument to detect changes within patients, was explored by assessing symptoms throughout an interval of 48 h. This was analysed by Wilcoxon test for paired groups.

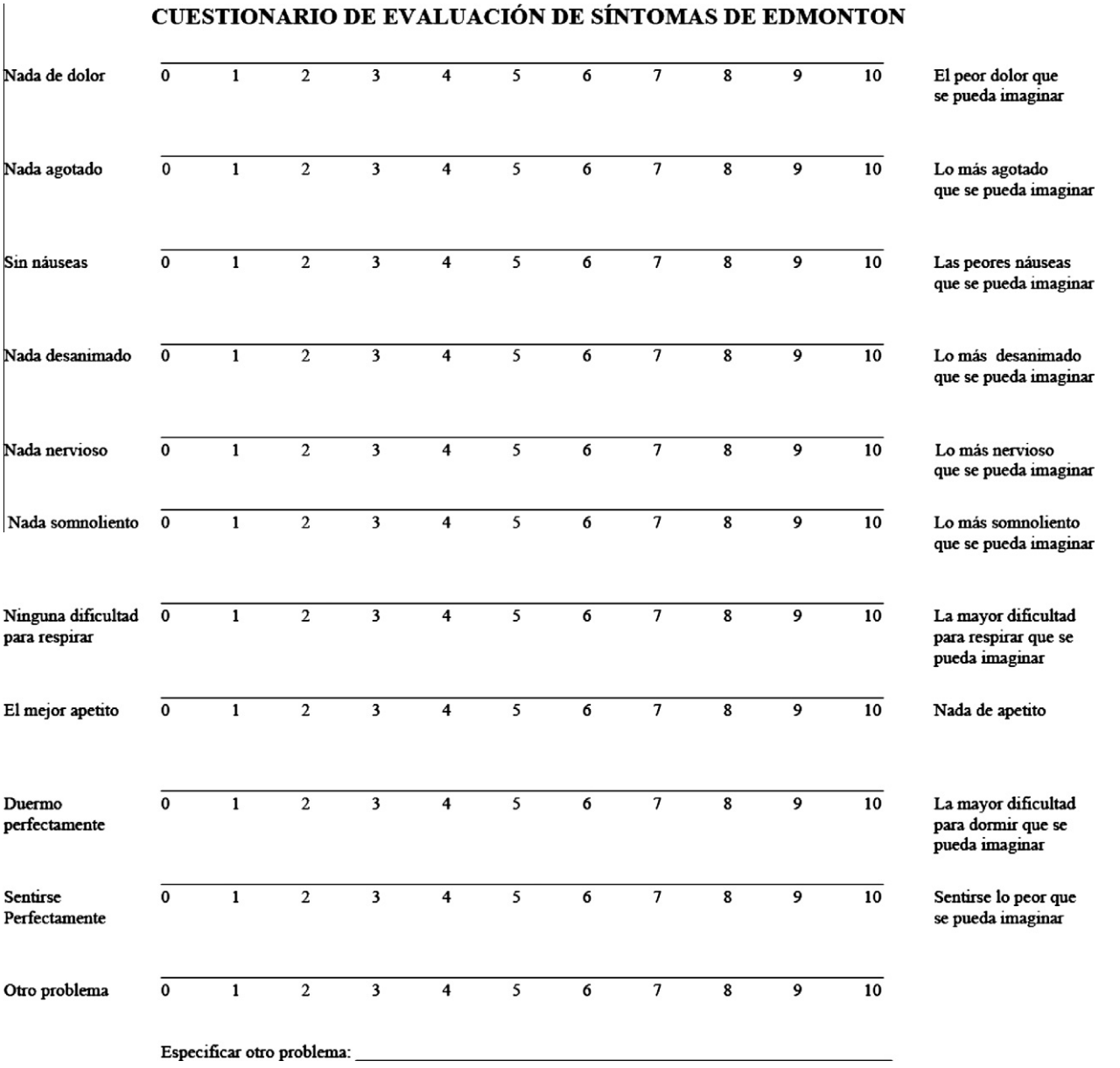
Utility was measured in 171 patients by the rate of responses obtained and the time required to complete the study; 40 patients were also asked to describe their perception of the ESAS.

All analyses were performed using Statistical Package for the Social Sciences (SPSS) 15.0 and PEPI 4.0 statistics package[33] for the Kappa calculation with a confidence interval of 95%.

3. Results

3.1. Translation and cultural adaptation

The Spanish version of the ESAS is shown in Fig. 1. Through the process of translation, difficulties in understanding the terms needed to explore the concepts of depression and anxiety were detected. "Depression" in Spanish could possess certain negative connotations that may result in an under-rating of the symptom in visual numerical scales (the same principle also applies to the term "anxiety", although on a slightly lesser scale). Because that the translation committee decided that it was necessary to carry out two further independent studies to clarify ways of assessing the concepts of "fatigue" "anxiety" and



CUESTIONARIO DE EVALUACIÓN DE SÍNTOMAS DE EDMONTON

Nada de dolor	0	1	2	3	4	5	6	7	8	9	10	El peor dolor que se pueda imaginar
Nada agotado	0	1	2	3	4	5	6	7	8	9	10	Lo más agotado que se pueda imaginar
Sin náuseas	0	1	2	3	4	5	6	7	8	9	10	Las peores náuseas que se pueda imaginar
Nada desanimado	0	1	2	3	4	5	6	7	8	9	10	Lo más desanimado que se pueda imaginar
Nada nervioso	0	1	2	3	4	5	6	7	8	9	10	Lo más nervioso que se pueda imaginar
Nada somnoliento	0	1	2	3	4	5	6	7	8	9	10	Lo más somnoliento que se pueda imaginar
Ninguna dificultad para respirar	0	1	2	3	4	5	6	7	8	9	10	La mayor dificultad para respirar que se pueda imaginar
El mejor apetito	0	1	2	3	4	5	6	7	8	9	10	Nada de apetito
Duermo perfectamente	0	1	2	3	4	5	6	7	8	9	10	La mayor dificultad para dormir que se pueda imaginar
Sentirse Perfectamente	0	1	2	3	4	5	6	7	8	9	10	Sentirse lo peor que se pueda imaginar
Otro problema	0	1	2	3	4	5	6	7	8	9	10	

Especificar otro problema: _____

Fig. 1 – Spanish version of the Edmonton Symptom Assessment System (ESAS). Original terms of the English version of the ESAS: No pain; Worst pain imaginable; No fatigue; Worst fatigue imaginable; No nausea; worst nausea imaginable; No depression; Worst depression imaginable; No anxiety; Worst anxiety imaginable; No drowsiness; Worst drowsiness imaginable; No shortness of breath; Worst shortness of breath imaginable; Best appetite; Worst appetite imaginable; Best sleep; Worst sleep imaginable; Best feeling of wellbeing; Worst feeling of wellbeing imaginable; Other problem.

"depression" with 100 patients in order to ensure that the terminology used was the most suitable and appropriate. These studies have recently been reported in detail elsewhere.[34,35]

After both studies we adopted the term "discouraged" (desanimado) to explore the concept of depression, and the term "nervous" (nervioso) to examine the concept of anxiety, although the alternative term of "disquiet" (intranquilidad) may also be used. As the term "fatigue" also possesses a number of different connotations in differing regions of Spain, the study explored the terms "tiredness" (cansancio), "exhaustion" (agotamiento) or "weakness" (debilidad).

3.2. *Participant's characteristics*

171 patients with advanced cancer participated in the study completing the ESAS at least one time. Demographic and clinical characteristics of the participants are available in Table 1. The mean age of the patients was 58 years (range 23–87 years). More than half of the patients were receiving chemotherapy or radiotherapy. Functional status was more than 70% in 54% of patients. In this sample, 48% of patients had been diagnosed with gastro-intestinal tumours. Table 2 shows the ESAS scores where asthenia was the symptom of more intensity (median = 4). The population under study was advanced cancer patients from different regions of Spain.

Table 1 – Characteristics of the sample.

Characteristics Mean age 58 years (range 23–87 years)		*n* = 171	%
Sex	Males	83	48.8
	Females	88	51.2
Type of tumour	Gastrointestinal	81	47.9
	Breast	24	13.
	Gynaecological	21	10
	Lung	23	10.9
	Haematological	13	6
	Others (genito-urinary, head and neck, melanoma)	13	8.5
Tumour status	Locally advanced	78	55.9
	Disseminated	93	44.1
Oncological treatment	Chemotherapy	134	82.5
	Radiotherapy	7	3.3
	Chemotherapy and radiotherapy	4	1.9
	No chemotherapy or radiotherapy	26	12.3
Reason for palliative care consultation	Pain	38	20.7
	Anxiety and depression	19	9.8
	Asthenia	14	7.6
	Anorexia, *cachexia*	3	1.6
	Disquiet	3	1.6
	Dyspnoea	1	0.5
	General deterioration	5	2.7
	Discharged	5	2.7
	No palliative care enquiry	71	52.8
KPS (Karnofsky)	30–40	19	9
	50–70	84	44.5
	80–100	68	54.5
Type	Outpatients	114	72.9
	Inpatients	57	27.1
Level of education completed	Higher	78	46.4
	Intermediate	77	46.4
	Basic	16	7.6

Table 2 – ESAS scores in first application and at the retest time.

	ESAS scores: median and [interquartile]	
	First application	Retest
Pain	2 [0–3]	2 [0–3]
Asthenia	4 [1–6]	4 [2–6]
Nausea	0 [0–0]	0 [0–0]
Depression	2 [1–5]	2 [0–5]
Anxiety	1 [0–4]	2 [0–3]
Drowsiness	2 [0–4]	2 [0–4]
Shortness of breath	0 [0–0]	0 [0–0]
Appetite	2 [0–5]	2 [0–5]
Insomnia	3 [0–5]	3 [1–5]
Well-being	3 [2–5]	3 [2–5]

3.3. *Psychometric aspects*

Table 3 presents the psychometric properties measured in the Spanish version of the ESAS. *Internal consistency* was measured for 171 patients using Cronbach's Alpha, obtaining a coefficient of 0.75 (95% CI: 0.70–0.81). On eliminating ESAS items one-by-one, it was found that none of them significantly modified the value for Cronbach's alpha, meaning that no single item distorted, nor was vital to ensure the internal consistency of the survey. To an extent, the items 'weakness' ($\alpha = 0.70$) and 'feeling of well-being' ($\alpha = 0.70$) both contributed to the scale's internal consistency. However, the items 'difficulty sleeping' ($\alpha = 0.78$) and 'difficulty breathing' ($\alpha = 0.76$) contributed less to the consistency of the scale.

The correlation of the item 'feeling of well-being' was also evaluated with the sum of the other items and a significant correlation between the two variables was found (Spearman's Rho $r = 0.73$) (95%CI: 0.64; 0.79). However, some patients with higher scores in the sum of the specific items (pain, fatigue, nausea, depression, anxiety, drowsiness, shortness of breath, appetite, difficulty in sleeping), did not score so highly in the item 'feeling of well-being'.

The *test–retest* reliability was assessed with 146 patients, within 0 to 4–6 h. This was measured by means of Spearman's correlation which obtained a different correlation in each item, oscillating from 0.65 to 0.94. The most stable items were 'difficulty sleeping' (0.94) and 'weakness' (0.90). The items with the lowest correlations (i.e. greatest change between the two time periods) were 'pain' (0.73), 'nausea' (0.71) and 'drowsiness' (0.65). To investigate whether there was concordance between the items as well as correlation, Lin's test was carried out and demonstrated a very high level of concordance (0.92) (95%CI = 0.89 a 0.92).

Concurrent validity was studied in 90 patients, comparing seven items on the ESAS with the equivalent items (fatigue, nausea, depression, anxiety, shortness of breath, appetite, difficulty in sleeping) in the RSCL. Both tools were completed at the first administration stage. The ESAS was administrated first, followed by the RSCL. A comparison between the two measures was obtained for seven of the ten symptoms contained within the ESAS. No items were found on the RSCL that could be compared with 'drowsiness' and 'pain'. The ESAS item 'well-being' cannot be compared with the quality of life item of the RSCL due to a technical error in the transcription of the questionnaire (the error was limited at this item of the 39 items of RSCL). The associations between the two measures was analysed using the Weighted Kappa Weight, with scores ranging from 0.45 to 0.66, with the exception of 'depression' and 'anxiety', which when explored with the terms 'discouraged' (desánimo) and 'nervous' (nervioso) demonstrated a lower level of correlation (0.32–0.35).

Discriminant validity of the ESAS tool was evaluated ($n = 171$) by measuring whether the ESAS scores differed, depending on the patient's functional state using the KPS. Spearman's correlation was applied to each item on the ESAS with the patients' KPS. Significant negative correlations ($p < 0001$) were found for seven items from the ESAS with KPS (Spearman's Rho $rs = -0.27$–0.54), findings which suggest that when the KPS score was lower, (i.e. the patient's functional state was worse), the ESAS item score was higher. Nevertheless, no significant correlation with the KPS was found for the items: 'nausea' (Spearman's Rho $r = -0.12$), 'anxiety' (Spearman's Rho $r = -0.21$) or 'difficulty sleeping' (Spearman's Rho $r = -0.18$). Correlation between the scores of the ESAS for inpatients and outpatients was also

Table 3 – Psychometric properties of the Spanish version of ESAS.

Property		Instrument	*n*	Statistical test	Results
Reliability	Internal consistency	ESAS[a]	171	Cronbach's Alpha	0.75; CI 95% (0.70–0,81
	Stability: test–retest	ESAS[a] at 0 and 4–6 h	146	Spearman's Rho Lin test	$r = 0.65$–0,94 $r = 0.92$; CI 95% = 0.89–0.92
Validity	Concurrent validity	ESAS[a] and RSCL[b]	90	Weighted Kappa	Nervous and discouraged $r = 0.3$; Others symptoms $r = 0.45$–0.66
	Discriminant validity	ESAS[a] between outpatients and inpatients	171	Mann–Whitney U	Out and inpatients ($p < 0.001$)
		ESAS[a] in patients with different functional status		Spearman's Rho	Different Karnosky Performance StatusNausea and difficulty sleeping ($p > 0.01$)Other symptoms ($p < 0.01$)
Factor analysis		ESAS[a]	171	Promax oblique rotation	Soft physical domain: nausea (0.88), appetite (0.70), drowsiness (0.60) and weakness (0.48).Emotional domain: difficulty sleeping (0.80); anxiety (0.78), feeling of wellbeing and discouraged (0.50).Hard physical domain: pain (0.50) and dyspnoea (0.88)
Responsiveness		ESAS[a] 0 and 48 h	45	Wilcoxon test	Pain, weakness, discouraged and wellbeing ($p < 0.05$)Nausea, anxiety, drowsiness, difficulty sleeping, difficulty breathing, lack of appetite ($p > 0.05$)
Utility		Compliance	171	Descriptive analysis	Average time of completion: 5.5 min (range 3–20 min).Percentage of response: 99% of responses
		Survey on patient's opinion	40	Qualitative analysis	Patients think: ESAS is easy to fill-in

[a] ESAS: Edmonton Symptom Assessment System.
[b] RSCL: Rotterdam Symptom Check List.

evaluated using the Mann–Whitney U test. A significant difference ($P < 0.001$) was found between the SDS of the ESAS for outpatients compared to inpatients, although higher SDS were demonstrated for inpatients (median = 34) than for outpatients (median = 17).

Factor analysis was carried out on the responses to the ESAS from 171 patients by means of promax oblique rotation to interpret the data. Three main domains were found in the ESAS: the first domain, described as 'soft physical symptoms' include nausea, appetite, drowsiness and weakness. The second domain, described as 'emotional components' include anxiety, depression or other symptoms such as sensation of well-being or difficulty in sleeping. The third domain, described as 'hard physical symptoms' include pain and difficulty in breathing.

Responsiveness was also evaluated in 45 patients on day 0 and after 48 h duration. The median ESAS score was performed by the Wilcoxon test, in which significant differences were found for the items of pain, weakness, discouragement and sensation of well-being ($p < 0.05$). Nevertheless, there were no significant differences in relation to the other symptoms.

In respect of utility, only one patient was unable to complete the survey because of fatigue. Patients took an average of 5.5 min to complete the survey (range 3–20 min). Almost all patients (97%) perceived the ESAS as a tool that was easy to complete due to clarity of instruction and order of question. Eight patients suggested that additional symptoms (diarrhoea 15%, xerostomia 11%, constipation 8%, several others 66%) should be included, whilst, 87.5% of patients indicated

that they preferred to complete the ESAS with assistance from a nurse.

4. Discussion

This study has produced the first Spanish version of one of the most widely used symptom evaluation tools in palliative care and evaluated the psychometric properties of the instrument in advanced cancer patients. The latest modified version of the ESAS had not previously been validated in either Spanish or English.

The Spanish version was the result of a complex method of translation and transcultural adaptation of the ESAS. Few data have been published on the translation method used to obtain the versions of the ESAS in other languages. Moro et al.[16] provide a schematic description of the translation process of the ESAS for its Italian version, although Jaturapatporn[19] presents only preliminary data about the translation of the ESAS into Thai. It is crucial to carry out the process of translation and transcultural adaptation before validating an instrument; using a symptom evaluation assessment that has not been psychometrically tested may do invalid the comparison of results with other similar studies.

Other ESAS validation studies involving patient samples between 65 and 69 years of age recommend undertaking further studies with younger patients; the average age of the patients in this study was 58 years. Almost half of the population in this study was diagnosed with gastro-intestinal tumours; in other studies, the most frequent diagnosis was lung or genitourinary cancer. The study group presented similar characteristics to those that could be expected to be seen at the Oncology Department of a teaching hospital. Viewing the variety of patient populations in which the validity of the ESAS has been tested, it could be suggested that the ESAS is useful for patients of different ages, with different types of advanced cancer; the broad levels of the KPS in this population also suggest that similar results could be found at previous stages of the disease.

Almost all patients were able to complete the survey. In other ESAS validation studies the response rates were also very high, at 97% and 100%, respectively. In studies carried out with palliative care patients alone, the response rate was slightly lower. The high percentage of response in this study may be due, in part, to the patients' good functional status; it may also indicate that the ESAS is not too burdensome for patients. The support provided by the research nurse in assisting patients to complete the questionnaire cannot be underestimated.

This survey presents a comprehensive study on the psychometric properties of the ESAS. A comparison of the psychometric aspects obtained in this study compared with previous studies is shown in Table 4. An original analysis arising from this study was factor analysis. Previous studies have focused on examining possible clusters in patients with bone metastases.[36] However, there are no studies that focus on assessing the internal structure of the survey or whether there was any correlation between the symptoms. Three domains were detected: 'soft physical', 'emotional' and 'hard physical'. The association that was found between difficulty in breathing and pain in the third domain might be due in part to the more severe impact that these symptoms produce compared to other symptoms.

Another unique analysis was the correlation between the item 'feeling of well-being' with the sum of the rest of the individual items. A high correlation was found between the two scores. This correlation suggests that the single item 'well-being' of the ESAS could be interpreted as a kind of global quality of life index supporting similar findings from recent studies using ESAS and the Functional Assessment of Cancer Therapy – General (FACT-G).[37] Other studies have used the symptom distress score (SDS) as an overall measure of all symptomatology, including 'feeling of well-being'. Future studies may wish to focus on examining the differences between the scores for total distress (SDS) and the item 'feeling of well-being'.

When measuring concurrent validity of the ESAS with the RSCL, it was found that the psychological items 'anxiety' and 'depression' correlated with weak score (0.35 and 0.32). This suggests that the method of asking about the symptom might actually serve to hide the intensity of that symptom, especially in relation to psychological symptoms. The fact that the terms used to explore depression in the RSCL (depressed feelings) and in the ESAS (discouraged) were different should also be fully taken into account. This is the reason proposed by Chang et al.[11] to explain the different responses given by patients for psychological symptoms when different terms are used to evaluate them. The results both in this study and in the one undertaken by Chang et al.[11], demonstrate that in order to evaluate symptoms effectively (especially psychological ones such as depression), use of the correct terminology is of enormous importance. All of this confirms the need to choose words that are culturally appropriate to explore different symptoms, as has been shown to be the case in previous studies.

Significant changes were detected in the scores for pain, weakness, discouragement and feeling of well-being at 0 and 48 h, respectively. Some studies of the ESAS measure the detection of change in symptoms within the patient at intervals of three and seven days.[38] For example, in the study undertaken by Moro et al. (1998), a significant difference was found after seven days of evaluation, whilst in the study undertaken by Rees et al.[12], a significant difference was also detected after five days of evaluation. The present study coincides with Moro et al.[16] in terms of the characteristics of the study as opposed to the one conducted by Rees et al.[12] where the performance statuses of the patients were different. It may be suggested, therefore, that the ESAS helps to evaluate changes of symptoms over periods of time. Further studies need to be carried out to explore these changes in a comprehensive way, considering a wider range of factors that could influence change in symptoms.

In respect of utility, most of the patients completed the survey in a relatively short time. This coincides with the time taken to complete the survey described in other studies and demonstrates the suitability of this instrument for clinical practice. The perception of the patients confirmed that the ESAS is easy to complete, reinforcing similar results found in other studies.[39] Many patients commented that having a healthcare professional ask them the questions helped them

Table 4 – Comparison of studies on psychometric properties of versions of the ESAS in different languages.

Psychometric aspects		Bruera 1993[25]	Philip 1998[8]	Nekolaichuk[15]	Chang 2000[11]	Pautex 2003[17]	Stromgren 2002[40]	Moro 2004[16]	Davison 2006[41]	Carvajal et al.
Language		English $n = 34$	English $n = 40$	English $n = 32$	English $n = 240$	French $n = 42$	English $n = 171$	Italian $n = 241$	English $n = 507$	Spanish $n = 171$
Reliability	Test–retest	1 h $r = 0.6–0.9$		24 h $r = 0.62–0.87$ (3 raters, 1 application)	24 h $r = 0.86$ 1 week, no difference			24 h $r = 0.4–0.8$	1 week $r = 0.7$	4–6 h, $r = 0.65–0.94$ Lin test $r = 0.92$
	Cronbach Alpha				0.79					0.75
	Inter-rater reliability			2 professionals and a family caregiver, $p < 0.05$		3professionals, $p < 0.05$				
Validity	Content validity						ESAS and medical records ($p > 0.1$)			
	Concurrent validity[a]	STAS $r = 0.7–0.9$	RSCL, BPI $r = 0.4–0.6$		MSAS, $r = 0.5–0.7$; FACT, $r = 0.5–0.7$			SDS, $r = 0.4–0.8$	KDQOL-SF $r = 0.5–0.7$	RSCL, $r = 0.3$, anxiety and depression 0.45, others 0.66
	Discriminant validity				Out and inpatients ($p < 0.01$); Karnosfky PS ($p < 0.001$)			Out and inpatients ($p < 0.01$); Karnosfky PS $p < 0.001$		Out and inpatients: all the symptoms $p < 0.01$, except nausea and sleep $p > 0.01$; Karnosfky PS $p < 0.01$
Factor analysis										3 Factors was found: severe symptoms (pain, dyspnoea), physical and psychological
Respon-siveness								Day 0 and day 7; no significant difference		Day 0 and 48 h later ($p < 0.05$)
Utility[b]							$n = 267$, 67% responses, 57% completed			Average time of completion 5.5 min; responders: 99%; easy to complete 97% (in a group of 40 patients)

[a] Other tools citated: STAS: Support Team Assessment Schedule, RSCL: Rotterdam Symptom Check List, BPI: Brief Pain Inventory, MSAS: Memorial Symptom Assessment Scale, FACT: Functional Assessment of cancer Therapy, SDS: Symptom Distress Scale, KDQOL-SF: Kidney Dialysis Quality of Life-Short Form questionnaire.

[b] Also studied in Watanabe et al.[42] and 2009, with 48 and 20 patients respectively: time completion 6, 7 min, 85% patients consider it easy to complete.

to complete and understand the instrument, especially when completing it for the first time. It also provided them with an opportunity to discuss other aspects of their life or things which were of importance to them. For this reason, the ESAS may be perceived not only as an assessment tool, but also as a vehicle for intervention, since it enhances patient–professional communication.

Some methodological limitations of the study have to be taken into consideration. Almost half of the patients in the study were diagnosed with gastro-intestinal tumours, as is characteristic in this particular setting. Karnofsky Performance Status (KPS) was higher than 40% in 80% of patients, thus suggesting that some measures could be less representative for patients that have poor performance status. ESAS scores would be higher in these patients and the influence of higher scores on the psychometric properties was not studied.

It has been acknowledged that the researcher nurse provided significant support in helping the patient to complete the ESAS survey. The results of the study demonstrate positive results with the procedure used. However, completing the ESAS without assistance may produce different results, and is an issue that requires further consensus between experts and increased clarification.

In conclusion, a Spanish version of the ESAS has been shown to be valid, reliable, responsive and feasible with adequate psychometric properties in advanced cancer patients. This version is equivalent to the English version with similar psychometric properties.

Conflict of interest statement

None declared.

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