Brief Methodological Report

Validation of the French Version of the Edmonton Symptom Assessment System



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Abstract

Context. The Edmonton Symptom Assessment System (ESAS) is a brief, widely adopted, multidimensional questionnaire to evaluate patient-reported symptoms.

Objectives. The objective of this study was to define a standard French version of the ESAS (F-ESAS) to determine the psychometric properties in French-speaking patients.

Methods. In a first pilot study, health professionals (n = 20) and patients (n = 33) defined the most adapted terms in French (F-ESAS). In a prospective multicentric study, palliative care patients completed the three forms of F-ESAS (F-ESAS-VI, F-ESAS-VE, and F-ESAS-NU, where VI is visual, VE, verbal, and NU, numerical), the Hospital Anxiety and Depression Scale. All patients had a test-retest evaluation during the same half-day. Standardized distraction material was used between each scale.

Results. One hundred twenty-four patients were included (mean age [\pm SD]: 68.3 \pm 12; 70 women; 54 men). Test-retest reliability was high for all three F-ESAS, and the correlation between these scales was nearly perfect (Spearman n = 0.66-0.91; P < 0.05). F-ESAS-VI, F-ESAS-VE, and F-ESAS-NU performed similarly and were equally reliable, although there was a trend toward lower reliability for F-ESAS-VI. Correlation between F-ESAS depression and anxiety and HADS depression and anxiety, respectively, were positive (Spearman rs = 0.38-0.41 for depression; Spearman rs = 0.48-0.57 for anxiety, P < 0.05). Among patients, 59 (48%), 45 (36%), and 20 (16%) preferred to assess their symptoms with F-ESAS-VE, F-ESAS-NU, and F-ESAS-VI, respectively.

Conclusion. The F-ESAS is a valid and reliable tool for measuring multidimensional symptoms in French-speaking patients with an advanced cancer. All forms of F-ESAS performed well with a trend for better psychometric performance for F-ESAS-of American Academy of Hospice and Palliative Medicine.

Key Words

Symptom, assessment, French, palliative care, ESAS, validity, reliability

Introduction

Patients with an advanced progressive disease experience a wide array of disease and treatment-related symptoms throughout the course of their illness, resulting in an ongoing need to improve both identification of these symptoms and communication about them. Several symptom assessment tools have been developed to help identify burdensome symptoms and to assess the success of their management.

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The Edmonton Symptom Assessment System (ESAS) quantifies the most common symptoms with a graphic display that facilitates interpretation and comparison over time.^{2,3} A recent bibliometric analysis of the ESAS highlights a rapid and multinational uptake of the tool over the past 15 years, where it is used for clinical, research, and administrative purposes. 4-9 In 2011, a revised version of ESAS (ESAS-r) was published. ESAS-r includes the same nine symptoms as ESAS, but the order of the symptoms has been changed and clarifications have been added. 10 Brief explanations allow for a better understanding of the meanings of tiredness (lack of energy), drowsiness (feeling sleepy), depression (feeling sad), anxiety (feeling nervous), and well-being (how you feel overall). Appetite was changed to lack of appetite. Since the first publication, ESAS has been translated and validated worldwide in a variety of different languages, such as Italian, Spanish, German, Thai, Korean, Japanese, Chinese. 11-18 The study aimed to define a standard French version of the ESAS and determine the psychometric properties of this standardized F-ESAS. Finally one secondary aim was to define what form: visual, verbal, or numerical was more adapted for patients with an advanced progressive disease.

Methods

Translation and Adaptation of the F-ESAS

As there are already six different—not validated—versions of the ESAS in French, the formal double-back translation process was not a good option. The six different French versions of the ESAS were collected and only disparate items where agreement was missing were selected (Appendix 1). These items were tiredness (in French: "fatigue" or "asthénie"), drowsiness (in French: "somnolent" or "envie de dormir"), anxiety (in French: "anxiété" or "peur"), depression (in French: "dépression", "déprime" or "tristesse"), shortness of breath (in French: "dyspnée" or "peine à respirer"), and well-being (in French: "bien-être" or "se sentir bien").

As a next step, 20 experienced health professionals, consisting of physicians and nurses, working in the field of palliative care (palliative care units and consultation teams, in- and out-patient setting), in different parts of the French part of Switzerland and France were selected. Each health professional was asked to fill out a questionnaire to determine the most comprehensible and adapted terms. They were asked to choose the most comprehensible and adapted terms. Agreement on the terms was found after the first round (all health professionals selected the same items) and on the basis of these feedbacks the first version of the F-ESAS was created.

Finally, 33 patients with an advanced progressive disease, hospitalized in the Geneva University Hospitals, were interviewed using a short questionnaire to elicit their opinion on the first version of the F-ESAS. Patients were asked to quote their agreement on the items and their definitions on a Likert scale (0 = no agreement at all to 4 = full agreement). The mean scores on the scale were 3.3/4 for anxiety and 3.8/4 for well-being. According to these results, this version has been selected for the psychometric analysis.

An explanatory leaflet, including short definitions of the items, was created by an experienced neuropsychologist and was used by the health care professionals to explain to the patients how they should complete the F-ESAS in a standardized way.

Psychometric Analysis F-ESAS

Participants. The study was performed between April 2011 and June 2014 in different out- and inpatient specialized palliative care settings in the French part of Switzerland and in France. Inclusion criteria were patients with advanced cancer, older than 18 years, and who had their symptoms stabilized (no treatment modification in the last 24 hours). They had to be either hospitalized in a palliative care unit or followed by an in- or outpatient palliative care consultation team. Exclusion criteria were impaired cognitive function based on the Mini-Mental Status Examination <24 or the short orientation memory concentration test (TELECOM >11), severe sensorial impairment, or if they were not speaking fluently French. 19,20

The demographic and disease-related data collected were age, gender, level of education, main disease, palliative care setting, and cognitive assessment. Comorbidities of patients were assessed with the Cumulative Illness Rating Score.²¹

A research nurse screened current and new admissions in each palliative care setting for study eligibility. Before data collection, she informed eligible patients about the study and obtained written consent. The F-ESAS was explained to the patient by the research nurses using the standard explanation text and the patient rated the current intensity of the different symptoms.

Reliability. The internal consistency of the F-ESAS was measured by calculating the Cronbach 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) within the ESAS and the item "feeling of well-being." Test-retest reliability was measured in an interval from 0 to 6 hours²²; 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

correlation coefficient. Sidak's adjustment was applied to calculate correlation's significance levels.

Validity Was Examined by Concurrent Validity. As no other symptom assessment tools are validated in French, three items, anxiety, depression, and appetite, were selected for this analysis. The concordance between the Hospital Anxiety and Depression Scale depression and F-ESAS depression, the HADS anxiety, and the F-ESAS anxiety was calculated.²³ HADS consists of 14 questions, seven for anxiety and seven for depression. Each item was answered by the patient on a four-point (0–3) response scale with scores ranging from 0 to 21 for anxiety and 0 to 21 for depression.²⁴

Preferred ESAS Form

Numerical, verbal, and visual analog versions of the F-ESAS were created. Regarding the numerical F-ESAS, severity of each symptom was rated from 0 to 10 (0 = absence of symptom, 10 = worst possible intensity). The six-point Verbal Rating Scale, which consists of a list of adjectives included in the validated French version of the Mc Gill questionnaire, was selected. The order of the presentation of the three forms was randomized. Standardized distraction material was used between each presentation. Thereafter, the research nurses asked the patient to select his preferred scale.

Data Analysis

Sample size: a power analysis suggested that a minimum of 85 patients would provide 80% power (alpha = 0.5, r = 0.3). To compare patient characteristics, categorical variables were evaluated by chisquare or the Fisher's exact test as extended by Mehta when appropriate and the Kruskal-Wallis test or AN-OVA was used for continuous variables.

Ethics

The study was approved by our local ethics committee.

Results

One hundred twenty-four patients consented and completed the study. Participant characteristics are described in Table 1. Most were inpatients (89%), with a median age of 68.5 years, and approximately 60% were women. Main oncologic diseases were lung cancer (n = 30; 24%), breast cancer (n = 29; 23%), and gastrointestinal cancer (n = 26; 21%).

Average symptom intensities measured by the numerical F-ESAS are summarized in Table 2. Mean

Table 1
Patients' Characteristics (n = 124)

	20 7 1 10
Age, yrs (mean \pm SD)	68.5 ± 12
Gender, men/women, n	61/82
Education, n (%)	
Compulsory school	23 (19)
Diploma	69 (56)
University	32 (25)
Patient setting, n (%)	
In patient	
University Hospital Geneva	37 (30)
University Hospital Lausanne	19 (15)
PCU Fribourg (Chatel St-Denis)	18 (15)
PCU Valais (Martigny)	16 (13)
PCU Vaud (Riveneuve)	7 (6)
PCU France Passy	13 (10)
Outpatient	
Geneva	11 (9)
Lausanne	2 (2)
MMSE (mean \pm SD)	26.3 ± 2.2
CIRS (mean \pm SD)	13.9 ± 4.8
HADS anxiety (mean \pm SD)	7.5 ± 4.0
HADS depression (mean \pm SD)	7.4 ± 4.4

PCU = Palliative Care Unit; MMSE = Mini-Mental Status Examination; CIRS = Cumulative Illness Rating Score; HADS = Hospital Anxiety Depression Scale.

scores (SD) ranged from 0.9 for nausea (1.8) to 3.4 for appetite (2.5).

Reliability

The *internal consistency* of the F-ESAS measured by Cronbach alpha was 0.77. As part of the routine calculation of Cronbach alpha, one item at a time, making up the scale, is removed and the alpha is recomputed without this item to assess the influence of this precise item on the overall score. The removed item is fed back in the scale and the next item is then removed. Removing any of the nine items, one at a time, did not change the magnitude of the alpha, meaning that no single item distorted, nor was vital to ensure the internal consistency of the scale. Spearman correlation between the sum of specific items (pain, fatigue, nausea, depression, anxiety, drowsiness, shortness of breath, appetite) within the F-ESAS, and the item "feeling of well-being" was high (spearman correlation 0.52-0.78; P = 0.000).

Table 2
Mean Symptom Intensity and SD Measured by the Numerical F-ESAS During Assessment 1

	Mean (SD)
Pain	2.3 (2.1)
Fatigue	3.4 (2.6)
Nausea	0.9 (1.8)
Depression	1.7 (2.2)
Anxiety	2.1 (2.4)
Drowsiness	2.7 (2.6)
Dyspnea	2.2 (2.6)
Appetite	3.4 (2.6)
Well-being	2.8 (2.3)

The test-retest reliability was assessed with 124 patients and is described in Table 3. The most stable items were pain and appetite (0.88). The items with the lowest correlations (i.e., greatest change between the two time periods) were fatigue (0.67) and dyspnea (0.70).

Correlation between the three versions of F-ESAS was very strong (Spearman correlation ranging from 0.66 to 0.95; P < 0.001) (Table 4).

Concurrent Validity

A moderate (spearman correlation coefficient 0.38–0.45) but statically significant correlation emerged between the F-ESAS depression and the HADS depression score and the F-ESAS anxiety and the HADS anxiety (spearman correlation coefficient 0.48–0.57).

The preferred scale selected by the patient was in decreasing order, the verbal (n = 59; 48%), the numerical (45; 36%), and the visual analog (20; 16%) F-ESAS.

Discussion

This study has produced the first French validated version of one of the most widely used symptom evaluation tools in palliative care and evaluated the psychometric properties of the instrument: F-ESAS. This study has several strengths. It included a large sample size of participant's representative of French-speaking palliative care patients. Furthermore, it covered a population living at home and hospitalized in a palliative care unit. The cognitive abilities of the patients were measured systematically to avoid the inclusion of patients with cognitive impairment. Finally, in some previous studies, a proportion of patients have indicated that they preferred to complete the ESAS with assistance from health care professionals because this would help clarify uncertainties and could contribute to the accuracy of the ESAS.²⁷ Therefore, some standardized instructions before the scale administration were used.

Table 3

Spearman Correlations Between Assessments 1 and 2 for F-ESAS Numerical, Verbal, and Visual Analog ESAS

	<u> </u>			
	Numerical	Verbal	Visual Analog	
Pain	0.83	0.80	0.73	
Fatigue	0.67	0.69	0.72	
Nausea	0.83	0.71	0.61	
Depression	0.80	0.80	0.80	
Anxiety	0.79	0.74	0.70	
Drowsiness	0.81	0.70	0.72	
Dyspnea	0.82	0.70	0.70	
Appetite	0.88	0.82	0.76	
Well-being	0.75	0.73	0.71	

Table 4
Spearman Correlation Coefficient Among the Three
Forms of F-ESAS (Lower and Higher Range)

	Spearman Coefficient
Pain	0.77-0.91
Fatigue	0.71 - 0.86
Nausea	0.71 - 0.83
Depression	0.76 - 0.86
Anxiety	0.79 - 0.85
Drowsiness	0.80 - 0.89
Dyspnea	0.81 - 0.88
Appetite	0.79 - 0.91
Well-being	0. 66-0.82

F-ESAS showed favorable reliability. This finding is consistent with previous validation studies of other language versions of the ESAS or ESAS-r. Cronbach alpha coefficient in the present study was 0.77, and corresponding figures in other studies ranged from 0.86 to 0.88. All the three tested forms of F-ESAS performed similarly and were equally reliable. The well-being score correlated well with the sums of the other symptoms. These results are consistent with the Spanish validation of the ESAS (r = 073) and confirmed sufficient internal consistency of the F-ESAS. ¹²

Comparing the F-ESAS with other validated symptom assessment tools was one way to prove its validity.²⁸ However, in the absence of validated scales in French, we decided to select three items. Correlation between the HADS and the F-ESAS score for anxiety and depression were moderate, particularly for depression. These results are consistent with those of Vignaroli et al., who found that the ESAS was only moderately correlated with the HADS (r = 0.4), and those of Pantilat et al., who found that the ESAS was not well correlated with a 15-item Geriatric Depression Scale (r = 0.34). The moderate correlation noted in our study and others may be explained by the fact that the ESAS assesses symptoms at the instant of the assessment, whereas many other depression screening tools, including the HADS, assess symptoms over a period of one to two weeks.

Approximately half of the included patients preferred the verbal F-ESAS. According to these results, different forms of the ESAS should be available to allow the patient to select the scale that corresponds most to him.

This study has some limitations. First, the interval period for the test-retest validation was rather short. However, this allowed for more stability in the symptom because palliative care situations may change quickly. Second, the symptom intensities presented by the patients were relatively low, but it was expected as the aim of the study necessitated to include clinically stable patients. This fact is because of the characteristics of the studied population, and it would be useful to reproduce the study in another setting.

Finally, responsiveness, which evaluates the ability of an instrument to detect changes within patients and discriminant validity were not explored.

The numerical version of the F-ESAS is a simple validated tool that should be routinely promoted in different palliative care settings in French-speaking countries. Health care professionals should be familiar with this tool and use the standardized explanatory leaflet text to support the patients if needed.

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Appendix

 ${\it Appendix} \ 1 \\ {\it Summaries of the Different French Versions of ESAS}$

Summaries of the Different French Versions of ESAS			
Version 1			
Absence de douleur Absence d'asthénie Absence de nausées Pas déprimé Absence anxiété Absence de somnolence Très bon appétit Très bonne sensation de bi être Absence de dyspnée	Douleurs intolérables Très asthénique Très nauséeux Très déprimé Très anxieux Très somnolent Absence d'appétit en- Absence de sensation de bien-être Très dyspnéique		
Version 2	nes dyspheique		
Pas de douleur Pas de nausées Pas de peine à respirer Pas de fatigue Pas de somnolence Pas de manque d'appétit Pas anxiété Pas de déprime Je me sens bien Version 3	Douleurs maximales imaginables Nausées maximales imaginables Peine à respirer maximale imaginable Fatigue maximale imaginable Somnolence maximale imaginable Manque d'appétit maximal imaginable Anxiété maximale imaginable Déprime maximale imaginable Je me sens mal		
Pas de douleur Pas de nausées Pas de peine à respirer Pas de fatigue Pas de somnolence Pas de manque d'appétit Pas anxiété Pas de tristesse Je me sens bien	Pire douleur possible Pire nausées possibles Peine à respirer maximale imaginable Fatigue maximale imaginable Somnolence maximale imaginable Manque d'appétit maximal imaginable Anxiété maximale imaginable tristesse maximale imaginable Je me sens mal		
Version 4			
Pas de douleur Pas de nausées Pas de peine à respirer Pas de fatigue Pas de somnolence Pas de manque d'appétit Pas anxiété Pas de déprime Je me sens bien	Pire douleur possible Pire nausées possibles Peine à respirer maximale imaginable Fatigue maximale imaginable Somnolence maximale imaginable Manque d'appétit maximal imaginable Anxiété maximale imaginable Déprime maximale imaginable Je me sens mal		
Version 5			
Pas de douleur Pas de fatigue Pas de nausées Pas de tristesse Pas anxiété Pas de somnolence Pas de manque d'appétit Je me sens bien Pas d'essouflement Version 6	Pire douleur possible Pire fatigue possible Pire nausées possibles Pire tristesse possible Pire anxiété possible Pire somnolence possible Pire manque d'appétit possible Je me sens mal Pire essoufflement possible		
VCISIOII U			
Pas de douleur Pas de fatigue Pas de nausées Pas de déprime Pas anxiété Pas d'envie de dormir Pas de manque d'appétit Je me sens bien Pas dyspnée	Douleurs maximales fatigue maximale Nausées maximales Deprime maximale Anxiété maximale Envie de dormir maximale Manqué d'appétit maxinal Je me sens mal Pire dyspnée possible		