

Spanish Version of the Functional Outcomes of Sleep Questionnaire: Scores of Healthy Individuals and of Patients With Sleep Apnea–Hypopnea Syndrome

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OBJECTIVE: The main symptom of sleep apnea–hypopnea syndrome (SAHS) is excessive daytime sleepiness. The self-administered Functional Outcomes of Sleep Questionnaire (FOSQ) was designed to evaluate the impact of sleepiness on a patient's daily life. The aim of this study was to determine the scores of patients with SAHS and of healthy individuals on the Spanish version of the FOSQ and to assess its usefulness for evaluating the impact of excessive sleepiness in patients with suspected SAHS.

POPULATION AND METHODS: Thirty-one patients with SAHS diagnosed by conventional polysomnography and 31 healthy individuals were included in the study. The following data were collected: patient information; use of tobacco, alcohol, or street drugs; blood pressure; and sleep schedule. Sleepiness was assessed on the Epworth Sleepiness Scale and the impact of sleepiness on activities of daily living by the FOSQ.

RESULTS: Patients with SAHS (apnea–hypopnea index, 57) had a mean FOSQ total score of 88.7; healthy individuals had a mean score of 110.9 ($P < .001$). Significant differences were found between the 2 groups on all the FOSQ subscales, except for the one that measured social outcome. There was a moderate correlation between the 2 questionnaires ($r = -0.54$; $P = .01$) and between FOSQ and the AHI ($r = -0.39$; $P = .05$). While the capacity to predict SAHS based on receiver operating characteristic curves was greater for the Epworth Sleepiness Scale than for the FOSQ (area under the curve, 0.91 and 0.77, respectively), the diagnostic yield increased when both questionnaires were considered together (area under the curve, 0.96).

CONCLUSIONS: We obtained FOSQ reference scores for Spanish patients with SAHS and for healthy individuals. The study showed that the Spanish version of the FOSQ is a good instrument for assessing the impact of excessive sleepiness on activities of daily living in patients with suspected SAHS.

Key words: Sleep apnea. Excessive sleepiness. Functional Outcomes of Sleep Questionnaire (FOSQ).

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Valores de la versión española del Cuestionario del Impacto Funcional del Sueño (FOSQ) en sujetos sanos y en pacientes con apnea obstructiva del sueño

OBJETIVO: El síntoma principal del síndrome de apneas-hipopneas durante el sueño (SAHS) es la excesiva somnolencia diurna. El Functional Outcomes of Sleep Questionnaire (FOSQ) es un cuestionario autoadministrado que se concibió para evaluar la repercusión de la somnolencia en la vida diaria del paciente. El objetivo de este estudio es conocer los valores de la versión española del FOSQ y su utilidad para evaluar el impacto de la hipersomnolencia en personas con sospecha de SAHS.

POBLACIÓN Y MÉTODOS: Se incluyó en el estudio a 31 pacientes con SAHS diagnosticado mediante polisomnografía convencional y a 31 personas sanas. Se recogieron las siguientes variables: medidas antropométricas, hábitos tóxicos, presión arterial, fármacos y cuestionario sobre horarios de sueño. La somnolencia se estudió mediante la Escala de Somnolencia de Epworth y el impacto de la somnolencia en las actividades de la vida diaria mediante el FOSQ.

RESULTADOS: El valor medio del FOSQ total en los pacientes con SAHS (índice de apneas-hipopneas: 57) fue de 88,7 y en sanos, de 110,9 ($p < 0,001$). Se encontraron diferencias significativas entre ambos grupos en todas las subescalas del FOSQ, excepto en la que mide las relaciones sociales. Se obtuvo una correlación moderada entre ambos cuestionarios ($r = -0,54$; $p = 0,01$) y entre el FOSQ y el índice de apneas-hipopneas ($r = -0,39$; $p = 0,05$). Aunque la capacidad de predicción de presentar SAHS, calculada mediante curvas de eficacia diagnóstica, fue mayor para la Escala de Somnolencia de Epworth que para el FOSQ (área bajo la curva = 0,91 y 0,77, respectivamente), el rendimiento diagnóstico aumentaba al considerar conjuntamente ambos cuestionarios (área bajo la curva = 0,96).

CONCLUSIONES: Se han obtenido valores de referencia del FOSQ en pacientes con SAHS y en sujetos sanos de nuestro medio. Con este estudio se demuestra que la versión española del FOSQ es un buen instrumento de evaluación del impacto de la somnolencia en las actividades de la vida diaria en personas con sospecha de SAHS.

Palabras clave: Apnea obstructiva del sueño. Somnolencia excesiva. Functional Outcomes of Sleep Questionnaire (FOSQ).

Introduction

Sleep apnea-hypopnea syndrome (SAHS) is the most common sleep-related breathing disorder. According to a study carried out in the United States of America, it affects from 1% to 4% of the adult population¹ and a survey carried out in Spain showed the prevalence of the disease (defined by an apnea-hypopnea index [AHI] >5 accompanied by excessive daytime sleepiness) to be 6.5%.²

SAHS is characterized by repeated episodes of upper airway obstruction that produce oxygen desaturations and arousals leading to fragmented nonrestorative sleep. The most notable consequences of SAHS are excessive daytime sleepiness, cognitive deficit,³ decreased quality of life,⁴ and increased risks of cardiovascular^{5,6} and cerebrovascular complications⁷ and of traffic accidents.⁸ Excessive daytime sleepiness is the main and most common symptom. Such clinical tools as the multiple sleep latency and maintenance of wakefulness tests attempt to assess daytime sleepiness objectively. Both are costly and complex. One subjective test is the Epworth Sleepiness Scale, a self-administered questionnaire that is easy to use.⁹ It measures propensity to fall asleep and has proven very useful for detecting excessive daytime sleepiness in patients with suspected SAHS, for quantifying severity of excessive sleepiness, and for evaluating response to treatment.¹⁰

In 1997 the Functional Outcomes of Sleep Questionnaire (FOSQ)¹¹ was developed to evaluate the impact of excessive sleepiness on activities of daily living or, in other words, the functional impact of sleepiness. The FOSQ is a self-administered questionnaire that evaluates the following domains: social outcome, intimacy and sexual relationships, activity level, vigilance, and general productivity. In this way it gives additional information on the patient's general state of health and complements the evaluation of sleepiness provided by the Epworth scale. It has been shown to be a valid instrument based on its ability to discriminate between individuals with and without sleep disorders and because of its reliability (Cronbach α coefficient >0.7), as well as on comparison with such generic questionnaires as the 36-item short form general health questionnaire (SF-36).¹² The FOSQ was adapted to Spanish using the translation-back translation method with a panel of patients and a committee of experts.¹² However, as far as we know, reference scores for Spanish patients with SAHS and healthy individuals are yet to be determined.

The objectives of this descriptive study were to determine FOSQ scores for patients with SAHS and for healthy individuals and to evaluate the usefulness of the Spanish version for assessing the impact of excessive sleepiness on activities of daily living in patients with suspected SAHS.

Populations and Methods

Population

This case-control study included 31 consecutive patients diagnosed with SAHS who had not yet initiated continuous positive airway pressure treatment and 31 healthy volunteers (matched for age and sex with the patient sample) recruited from

hospital staff (health care personnel and others). Those with SAHS-related symptoms (snoring, apneas, sensation of suffocation during the night, feeling unrefreshed after sleep, and daytime sleepiness) were excluded, as were health care staff who undertook 24-hour calls, so that the results of the sleepiness and quality of life questionnaires would not be affected by any secondary sleep disorder or alteration in sleep schedule.

Patients with SAHS were diagnosed by conventional polysomnography (PSG). The following parameters were monitored: oronasal airflow using a thermistor, respiratory effort using thoracoabdominal bands, arterial oxygen saturation using pulse oximetry, electrocardiogram, 2 electroencephalogram channels (A1-C4 and A2-C3), submental electromyogram, and electrooculogram. Apnea was defined as the cessation of oronasal airflow for 10 seconds or more¹³ and hypopnea as a decrease in oronasal airflow lasting 10 seconds or more associated with a fall in oxygen saturation of at least 4% and/or arousals¹⁴ (defined as the sudden appearance in the electroencephalogram of an α rhythm lasting at least 3 seconds and accompanied by an increase in electromyographic activity during a sleep period). Patients were considered to have SAHS if the AHI was 10 or more. Sleep staging was scored manually according to the criteria of Rechtschaffen and Kales.¹⁵ A minimum recording time of 6 hours and a minimum total sleep time of 3 hours were required.

Study Variables

The following variables were analyzed: age, anthropometric characteristics (weight; height; body mass index [BMI]; neck, waist, and hip circumference), smoking and drinking habits, use of sedatives, systolic and diastolic blood pressure, educational level, medical history, and drug treatments. The presence of depression was determined by asking participants about history of depression and by the need for medication.

Sleep Schedule

All participants completed a questionnaire on their sleep schedules in order to determine their habits and hygiene. The questionnaire included questions on the number of hours slept on work and nonwork days, as well as naps and their duration.

Evaluation of Sleepiness

The Spanish version of the Epworth scale¹² was used to evaluate sleepiness. It includes 8 questions on the likelihood of falling asleep in various situations, such as reading, watching television, or speaking. Each question has 4 possible responses that are assigned a value between 0 and 3. The total score is obtained by adding up the values for all options. The minimum score is 0 (no sleepiness) and the maximum, 24 (incapacitating sleepiness).

The degree of sleepiness was classified by the study physician as mild, moderate, or severe in accordance with the system recommended by the American Thoracic Society (ATS).¹³

The impact of excessive daytime sleepiness on activities of daily living was evaluated using the Spanish version of the FOSQ. This questionnaire consists of 30 questions divided into 5 domains: general productivity (8 items), social outcome (2 items), activity level (9 items), vigilance (7 items), and sexual relationships and intimacy (4 items). The individuals surveyed are asked whether they experience difficulties in carrying out activities of daily living because they feel tired or sleepy. The questionnaire includes an explanation that the words "tired" and "sleepy" refer to the feeling of being unable to keep one's eyes

TABLE 1
Characteristics of the Study Subjects*

	Patients With SAHS	Healthy Individuals	P
Mean (SD) age, y	53.7 (8.8)	51.6 (9.7)	.642†
Sex, males	27 (87)	25 (81)	.49†
More than 8 years of education	14 (45)	18 (58)	.31†
AHI	57.3 (21.7)		
BMI	32.4 (6.3)	28 (3.6)	<.001†
SBP, mm Hg	142.2 (14)	134.5 (12.5)	.042†
DBP, mm Hg	92.5 (10.8)	81.7 (11.3)	<.001†
Depression	3 (10)	0	.078‡
Sedative use	5 (16.1)	1 (3)	.088‡

*Data are expressed as means (SD) except for qualitative variables, which are expressed as number of patients (percentage). AHI indicates apnea-hypopnea index; BMI, body mass index; DBP, diastolic blood pressure; SBP, systolic blood pressure; SAHS, sleep apnea-hypopnea syndrome.

†Mann-Whitney test for independent samples.

‡ χ^2 test.

TABLE 2
Sleep Schedule Questionnaire*

	Patients With SAHS	Healthy Individuals	P†
Sleep on work days, min	423.9 (55.2)	420.2 (51.7)	.971
Sleep on nonwork days, min	437 (133.9)	462.6 (54.1)	.885
Naps on work days, min	75 (16-120)	30 (15-60)	.279
Naps on nonwork days, min	90 (30-120)	30 (15-60)	.032

*Data are expressed as means (SD) or medians (interquartile range). SAHS indicates sleep apnea-hypopnea syndrome.

†Mann-Whitney test for independent samples.

open or one's head up due to sleepiness, the need to doze, or an urgent need to sleep. The explanation stresses that tiredness does not refer to the feeling one might have after exercise. Each item has 4 possible responses: "no difficulty," "slight difficulty," "moderate difficulty," or "considerable difficulty." For some items there is an alternative response that the activity is not performed for reasons other than sleepiness. The score for each subscale is obtained by calculating the mean score for the items that comprise it. Items with no response or those that do not apply are not included in the calculation of the mean. In our study, the score was obtained according to the instructions of the authors of the original questionnaire. The score for each subscale has a minimum value of 0 (maximum functional impact) and a maximum of 24 (no impact). The total score ranges from 0 to 120 and is obtained by adding up the scores from each of the 5 subscales.

Statistical Analysis

The statistical analysis was carried out with the SPSS statistical package, version 12.0. The results obtained were expressed as means unless the data did not have a normal distribution, in which case they were expressed as medians and interquartile ranges. Between-group comparisons were performed using the χ^2 test for qualitative variables and the Mann-Whitney test for independent samples of quantitative variables. The correlation between variables was assessed using the Spearman correlation coefficient. A logistic regression model was constructed with patient versus control status as the dependent variable and all the variables considered possible predictors of sleep apnea as independent variables: ATS-recommended classification of degree of daytime sleepiness, total FOSQ score, and Epworth score. Finally, in order to assess the sensitivity and specificity of the various cutoff points for the variables studied, receiver operator characteristic curves were constructed and the area under the curve (AUC) calculated. Statistical significance was established at $P < .05$ in all the analyses.

Results

No significant differences were found between the 2 groups with respect to age, sex, or educational level. In the SAHS group, mean (SD) AHI was 57.3 (21.7). BMI and neck, hip, and waist circumferences were significantly greater ($P < .05$) and both systolic and diastolic blood pressures significantly higher ($P < .05$) in the SAHS group than in the control group (Table 1). The proportion of participants with a history of depression or sedative use was higher in the SAHS group, although differences were not significant ($P > .05$) (Table 1).

Comparative analysis of the sleep schedules of the 2 groups showed that patients with SAHS took more and longer naps. Among participants who took naps, nap duration was longer in the SAHS group. Differences were significant for naps taken on nonwork days (Table 2).

The mean Epworth score was significantly higher (12.7 [3.8] compared to 5.6 [3.3]; $P < .001$) and the mean total FOSQ score significantly lower (88.7 [19.8] compared to 110.9 [9.8]; $P < .001$) in the SAHS group than in the control group. The score on each of the FOSQ subscales was lower in the SAHS group. Significant differences were found between the 2 groups in all but the subscale that measured social outcome (Table 3).

The correlation between the FOSQ and the Epworth scores was -0.54 ($P = .01$). In the SAHS group there was a weak to moderate correlation between FOSQ scores and AHI ($r = -0.39$; $P = .05$), but no correlation was found between Epworth scores and AHI ($r = 0.15$; $P = 0.4$) (Table 4).

The logistic regression model was constructed with the ATS-recommended classification of sleepiness and the Epworth and FOSQ scores. The Epworth scale and FOSQ values chosen as dichotomous variables were the

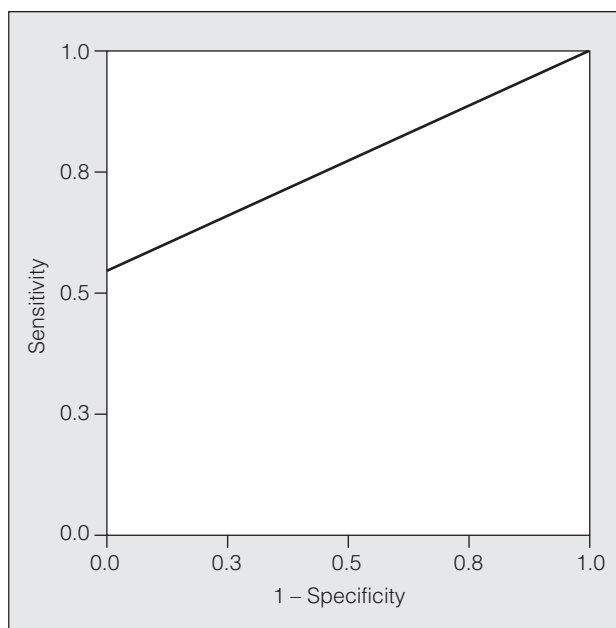


Figure 1. Receiver operating characteristic curve for the American Thoracic Society-recommended classification of sleepiness.

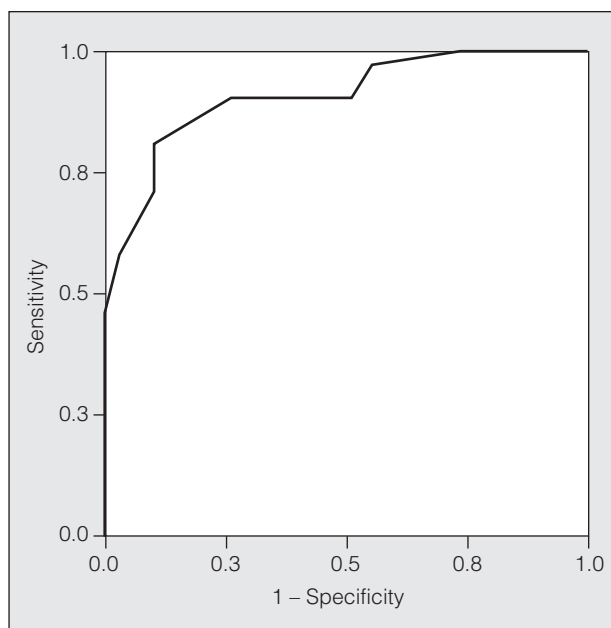


Figure 2. Receiver operating characteristic curve for the Epworth Sleepiness Scale.

cutoff points that had shown the best results in terms of specificity and sensitivity based on the receiver operating characteristic curves (cutoff point of 9 for the Epworth scale and 110 for total FOSQ-score). We found that both Epworth and FOSQ scores were significantly associated

with the probability of presenting SAHS ($P=.009$ and $P=.025$, respectively), while there was no significant association with the ATS-recommended classification (Figures 1-3).

TABLE 3
Evaluation of Sleepiness: Mean (SD) Scores on the Epworth Sleepiness Scale and the FOSQ*

	Patients With SAHS	Healthy Individuals	P^\dagger
Epworth Sleepiness Scale	12.7 (3.8)	5.6 (3.3)	<.001
FOSQ			
Total	88.7 (19.8)	110.9 (9.8)	<.001
General productivity	19.3 (4.5)	23 (1.9)	<.001
Social outcome	21.5 (5.5)	22.6 (2.9)	.227
Activity level	15.8 (4.5)	21 (3)	<.001
Vigilance	15.4 (5.5)	21.9 (2.9)	<.001
Sexual relationships and intimacy	18.3 (7.8)	22.3 (3)	.002

*SAHS indicates sleep apnea-hypopnea syndrome; FOSQ, Functional Outcomes of Sleep Questionnaire.

† Mann-Whitney test for independent samples.

TABLE 4
Spearman Correlation Coefficients for the Various Indicators of Severity of Sleepiness*

	AHI	Epworth Sleepiness Scale	Total FOSQ
AHI	1.000	0.159	-0.390 †
Epworth Sleepiness Scale	0.159	1.000	-0.548 ‡
Total FOSQ	-0.390 †	-0.548 ‡	1.000

*FOSQ indicates Functional Outcomes of Sleep Questionnaire; AHI, apnea-hypopnea index. † Significant correlation at the .05 level (2-tailed).

‡ Significant correlation at the .01 level (2-tailed).

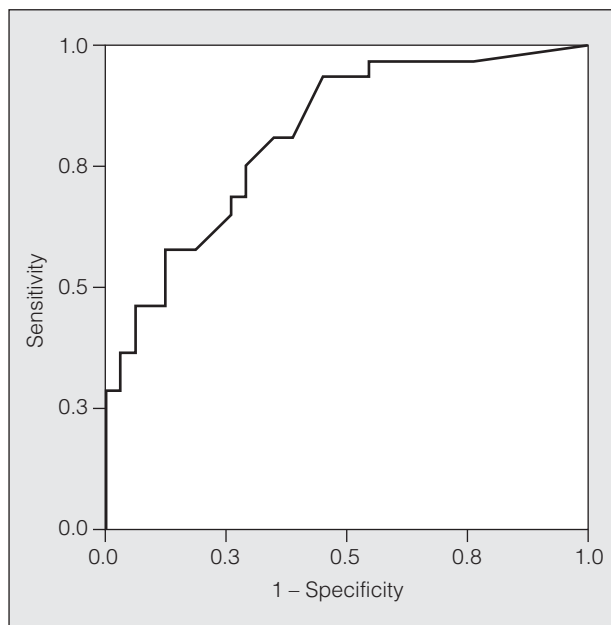


Figure 3. Receiver operating characteristic curve for the Functional Outcomes of Sleep Questionnaire.

scale had the highest predictive value (AUC, 0.91), while the predictive value of the total FOSQ score was intermediate (AUC, 0.81). They also showed the best cutoff point for prediction of a diagnosis of SAHS to be 9 for the Epworth score and 110 for the FOSQ score. Sensitivity was 81% for the Epworth scale and 93% for the FOSQ. Specificity was 90% for the Epworth scale and 59% for the FOSQ. Finally, the AUC, which was calculated from the probability of SAHS estimated using logistic regression, was 0.96. When both questionnaires were considered together, logistic regression showed a sensitivity of 93.5% and a specificity of 80.6%.

Discussion

The present study determined FOSQ reference scores for Spanish patients with SAHS and healthy individuals and showed that the Spanish version of the FOSQ is a good instrument for assessing the impact of excessive sleepiness on activities of daily living. Our interest in this questionnaire has gone hand in hand with a growing boom in instruments designed for the specific evaluation of various diseases with a view to furthering our understanding and improving treatment. The FOSQ was conceived as a specific questionnaire to measure the impact of excessive sleepiness on activities of daily living. Unlike such generic questionnaires as the Nottingham Health Profile and the SF-36, it has the advantage of being sensitive to clinical changes, thereby making it possible to measure the effect of treatment and to compare the results of various studies. Several studies have used the FOSQ to determine severity of SAHS and to evaluate the effectiveness of various medical interventions in patients with this disease.¹⁶⁻¹⁸

The well known association between SAHS and obesity was also observed in our study. Sixty-eight percent of the patients in the SAHS group were either overweight or obese (BMI \geq 27), compared to 52% in the control group.

There was also a significant difference in both diastolic and systolic blood pressure between patients and healthy individuals. These findings were consistent with reports from studies that have found a clear association between SAHS and hypertension and shown SAHS to be a risk factor for hypertension independent of other factors such as obesity.^{19,20} Also noteworthy were a greater prevalence of depression in the SAHS group and a greater consumption of sedatives and sleeping pills.

With regard to sleep schedule, we observed that while there was no difference in the number of hours of nighttime sleep between the 2 groups, those in the SAHS group took more and longer naps on nonwork days. This may suggest a sleep deficit in such patients.

A possible limitation of the present study is that while the control group subjects were selected from among healthy volunteers with no symptoms of SAHS (including snoring), they did not undergo PSG to rule out the disease entirely. Although the study would clearly have been more rigorous if PSG had been performed in the controls, both their BMIs and the Epworth scores were characteristic of a healthy population, suggesting that selection was appropriate.

The severity of excessive sleepiness assessed by the Epworth scale was significantly higher in the SAHS group, although the mean score obtained was somewhat lower than in other studies.^{21,22} Epworth scores for the control group (5.6 [3.3]) were similar to those found in the literature (5.9 [2.2]).⁹ The difference in total FOSQ scores between the 2 groups was also significant. There was evidence of functional impairment in 4 of the 5 domains of the FOSQ in the SAHS group, but not in the control group. The only domain not affected in the SAHS group was the one that reflected social outcome, and it must be borne in mind that this subscale may be less sensitive as it includes only 2 questions to determine the effect of excessive sleepiness on social role. These results confirm the impact of SAHS on the patient's state of health.

The absolute FOSQ scores obtained in patients and healthy individuals were somewhat higher than those reported for the original questionnaire of Weaver et al.¹¹ In the Spanish version, following the authors' recommendations, we applied a different scoring system from the original: in the original version, scores for each subscale range from 0 to 20, but in the Spanish version, the range is from 0 to 24. Applying the corresponding correction factor to the series of Weaver et al,¹¹ we would obtain a mean FOSQ score for healthy individuals of 107 instead of 89 (110 in our series) and 81 instead of 68 (89 in our series) for patients with SAHS.

Comparing the FOSQ with the Epworth scale using receiver operating characteristic curves, we observed that as a screening test the FOSQ was more sensitive than the Epworth scale and that its diagnostic yield was acceptable (AUC, 0.8), although not higher than that of the Epworth scale (AUC, 0.9). When the FOSQ and the Epworth scale were considered together, the AUC increased to 0.96. Sensitivity was higher for the FOSQ at 93.5% than for the Epworth scale (81.3%) but specificity, at 80.6% was lower in comparison with 90.1% for the Epworth scale. This is to say, although specificity is lower, sensitivity is considerably higher, increasing the FOSQ questionnaire's value for screening out patients who are not candidates for sleep studies.

The present study showed an acceptable correlation between the Epworth scale score and the FOSQ score and between the FOSQ score and the AHI. Thus, the FOSQ can provide additional information on how excessive sleepiness assessed by the Epworth scale affects patients' quality of life.

We also obtained FOSQ reference scores for Spanish patients with SAHS and for healthy individuals and showed that the Spanish version of the FOSQ is a good instrument for assessing the impact of excessive sleepiness on activities of daily living in patients with a clinical suspicion of SAHS. The questionnaire is short and easy to administer, characteristics that are essential for minimizing the effect of sleepiness during testing. We therefore recommend the use of the questionnaire as a qualitative and quantitative measure of the severity of SAHS and as a way of determining whether or not it might be reversed by the administration of specific treatment.

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