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Research Article

The Self-Perceived Medical Outcomes Study Sleep (MOS-S) Scale for the Detection of Overactive Bladder in the General Population

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- Overactive bladder
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- General population
- Screening

Abstract

Background: Overactive bladder (OAB) is usually associated with significant sleep disturbance.

Objective: This study analyzes the diagnostic performance of the self-perceived sleep quality Medical-Outcomes-Study-Sleep (MOS-S) scale as a screening tool for probable OAB (pOAB)

Methods: *Posthoc* analysis of a cross-sectional study in the Spanish general population with electronic data capture (Computer Assisted Web Interviewing [CAWI]), in subjects of both genders, and aged between 18-70 years old. pOAB patients were identified by a validated diagnostic algorithm. Quality and quantity of self-perceived sleep was measured with the MOS-S scale.

Results: A total of 2,035 subjects were analyzed (50.8% male, mean age: 52.7 years). Prevalence of pOAB was 16.4%. The total MOS-S score was higher in pOAB patients (38.2 [36.3 to 40.2] vs. 25.3 [24.6 to 26.1], p<0.001). Prevalence of pOAB increased with MOS-S score according to10%-intervals, from 3.5% to 41.2% (p<0.001). The odds ratio of pOAB adjusted by age and gender increased by 33% in each 10%-interval of deteriorating sleep quality [OR: 1.33 (1.27 to 1.41), p<0.001]. An adjusted MOS-S score of >31 had a sensitivity of 98.5% and a specificity of 90.7% [AUC=0.990 (0.986 to 0.993), p<0.001] to detect pOAB in 72.5% (68.4%-76.3%) of cases (positive post-test probability) and an error probability of 0.4% (0.2%-0.9%) to discard real pOAB (negative post-test probability).

Conclusions: The MOS-S scale to assess self-perceived quality of sleep seems to have ability as a screening tool to detect pOAB hidden in the general population. Faced with common complaints about the quality of sleep, clinicians should explore deeply patient's bladder health.

BACKGROUND

Overactive bladder (OAB) is a symptom syndrome consisting of an urgency to urinate with or without urinary urge incontinence (UUI), often associated with urinary frequency and nocturia [1]. OAB affects 20% of the global population over 40 years old [2,3]. This disorder results in an urge to urinate that negatively affects patient's life. Over 40% patients lose bladder control leading to incontinence [4]. Although the syndrome is not life-threatening, it is still an under-diagnosed disorder that remains undertreated [4,5]. Many subjects are afraid to seek medical advice for urinary incontinence because of social misconceptions and stigmas. Others are not aware that effective therapeutic approaches are available and therefore do not seek treatment [6]. Furthermore, not all subjects feel their symptoms are bothersome enough to warrant seeking treatment [7]. Finally, some patients choose not to mention their OAB symptoms for fear that assessment and treatment by a physician will cause more discomfort [8].

It is well known that OAB not only negatively impacts daily life, work competence, and quality of life, but also it is associated with significant sleep disturbance [6]. Urgency and nocturia were factors that independently affected sleep quantity and quality in OAB patients [9]. In addition, sleep disturbances tend to increase with age and are a common finding in the diagnosis of OAB [5]. Different scales and tools have been proposed for the measurement of sleep disturbance and its impact [10]. MOS-sleep (Medical Outcomes Study-sleep) scale, or MOS-S; is a self-administered scale that values self-perceived quality and quantity of sleep [10]. The MOS-S scale has been validated in several languages, including Spanish [11]. Given the demonstrated association between sleep disturbance and OAB, as well as the confirmed difficulties for effective detection and diagnosis of OAB syndrome, there is a need for the description and identification of useful screening tools [5]. Thus, the main objective of this study was to examine and evaluate the diagnostic performance of the MOS-S scale in the detection and screening of probable OAB in Spain.

METHODS

This is a *posthoc* analysis of an epidemiological, cross-sectional, observational study conducted in May 2012 based on an electronically-completed questionnaire. The aim of the original study was the cultural, linguistic and psychometric adaptation of the screening scales for overactive bladder OAB-V8 and OAB-V3in Spanish [12]. The study included 2,035 subjects of both genders, randomly selected from the general population and aged 18 to 70. The upper limit for age was 70 years old as it was not expected that subjects above that age would be familiar with the Internet. The baseline demographic and clinical characteristics may be found elsewhere [12]. The overall sample size and the age distribution of the subjects was set considering the age range representation of OAB prevalence in the Spanish population [2]. A Computer Assisted Web Interviewing (CAWI) method was used for the collection of data and completion of questionnaires [12]. The subjects were part of a population panel from a database owned by the consultancy firm Kantar Health Spain. This data base is representative of the Spanish population census. In each age and gender category all subjects had the same probability to be invited to participate, thus performing sampling without replacement. All subjects gave electronic informed consent prior to the completion of the questionnaire and scales that were administered serially. The protocol (code: PFI-OAB-2012-01) was approved by the corresponding Clinical Research Ethics Committee on March 28th, 2012 (approval A06-12).

The study also collected demographic data, habits and medical history. An automated algorithm for detection of probable OAB (pOAB) described by Coyne et al. and validated in Spanish by Brenes et al. was also administered [12,14]. The algorithm consisted of a structured questionnaire that explored the presence of cardinal symptoms of OAB (urgency, urgency with incontinence, nocturia, frequency, etc.). It also analyzed the level of discomfort/bothersome symptoms and the coping strategies developed by the patient. It was assumed that the presence of at least one of the cardinal symptoms, classified as troublesome, and with at least one coping strategy, justified a classification of pOAB. Also, subjects had to have a score of 8 or more in the OAB-V8 scale to be considered for pOAB classification. The MOS-S is a 12-item tool divided into 6 dimensions that evaluates sleep disturbance, snoring, sleep awakening due to a shortness of breath or headache, sleep adequacy, somnolence, and quantity of sleep/optimal sleep [10]. Global sleep disturbance index or summary composite score was calculated [10]. The "quantity of sleep" dimension was calculated with average hours of sleep per night reported by the subject. The scores of the dimensions and of the global disturbance index were converted to a 0 to 100 scalewith higher scores indicating more of the concept being assessed.

STATISTICAL ANALYSIS

A descriptive analysis was performed using frequency tables and measures of central tendency. To test the diagnostic performances of the MOS-S scale as a tool for detection of individuals with pOAB, a two-step statistical analysis strategy was followed. First the association of pOAB with MOS-S score summary and its dimensions was compared to subjects without pOAB using a general linear model (ANCOVA) with age and gender as covariates. In addition, associations of higher pOAB prevalence with worsening summary scores and with the MOS-S dimensions of "disturbed sleep""sleep adequacy" and "daytime sleepiness" were identified. This analysis was performed through binary logistic regression and also applying a linear trend Chi-squared test with gender and age as covariates and the presence of pOAB as a dependent variable. Once the association of pOAB with worse self-perceived sleep quality was determined, the ability or diagnostic performance of the overall MOS-S score was analyzed as a screening tool of patients with pOAB. Since OAB prevalence increased with age and female gender, a hierarchical linear regression model was used to calculate the summary MOS-S score adjusted for gender, age and their interaction. After the adjusted summary MOS-S score was calculated, a Receiver Operating Characteristic (ROC) curve analysis was applied to identify the cut-off that best optimized the classification of pOAB patients. From this point, estimates of diagnostic performance of the test were calculated for the overall sample and by gender [15]. These estimates included sensitivity, specificity, positive and negative predictive values, false positive and negative test accuracy, likelihood ratios of positive and negative tests and post-test odds of a positive and negative test. A graph that classifies patients with pOAB at different cut-offs was also built. All analyses were performed using the statistical package SPSS Statistics v19.

RESULTS

A total of 2,035 subjects were analyzed. The mean age of the population was 52.7 years and the distribution by gender was 1:1 (50.8% male). The automated algorithm depicted a 16.4% prevalence of pOAB in the overall sample. The patient-reported MOS-S components comparisons between pOAB and the general population are summarized in Table (1). The total score of MOS-S was higher in pOAB patients (38.2 [36.3 to 40.2] vs. 25.3 [24.6 to 26.1], $p<0.001$). All components of the MOS-S showed significant differences between pOAB patients and the general population (adjusted by age and gender). Sleep disturbance, somnolence, awaken short of breath and snoring were components with higher scores in the pOAB population, while mean number of sleep hours and sleep adequacy were higher in the general population (Table 1). The prevalence of pOAB increased with MOS-S score according to 10%-intervals from 3.5% to 41.2% (Chi-squared-linear: 142.5, $p<0.001$). This trend was summarized by an odds ratio of pOAB adjusted by age and gender that increases by 33% in each 10%-interval of deteriorating quality of sleep according to the MOS-S score (OR: 1.33 [1.27 to 1.41], $p<0.001$) (Figure 1). When focusing in different domains of the MOS-S scale, the same trend was significantly observed in sleep disturbance (OR: 1.29 [1.23 to 1.35], $p<0.001$) and somnolence (OR: 1.26 [1.20 to 1.33], $p<0.001$), while adequacy of sleep domain was reduced

Table 1: Patient-reported MOS Sleep Scale components in pOAB patients and in the general population.

	General population (n=1,703)	Probable OAB (n=332)	p-value
Sleep disturbance	23.03 (22.1, 23.9)	37.7 (35.5, 40.1)	0.000
Adequacy	58.7 (57.4, 60.1)	48.9 (46.2, 51.6)	0.003
Somnolence	27.5 (26.6, 28.3)	37.5 (35.3, 39.5)	0.000
Sleep hours per night (0-24)	6.8 (6.7, 6.8)	6.5 (6.4, 6.6)	0.002
Awaken short of breath	11.8 (10.8,12.7)	23.9 (21.33, 26.6)	0.001
Snoring	38.5 (37.0, 39.9)	45.8 (42.4, 49.1)	0.001
General index sleep problems	25.3 (24.6, 26.1)	38.2 (36.3, 40.2)	0.000

Values are means with 95% confidence interval. P-Values adjusted for age and gender.
OAB: Overactive bladder.

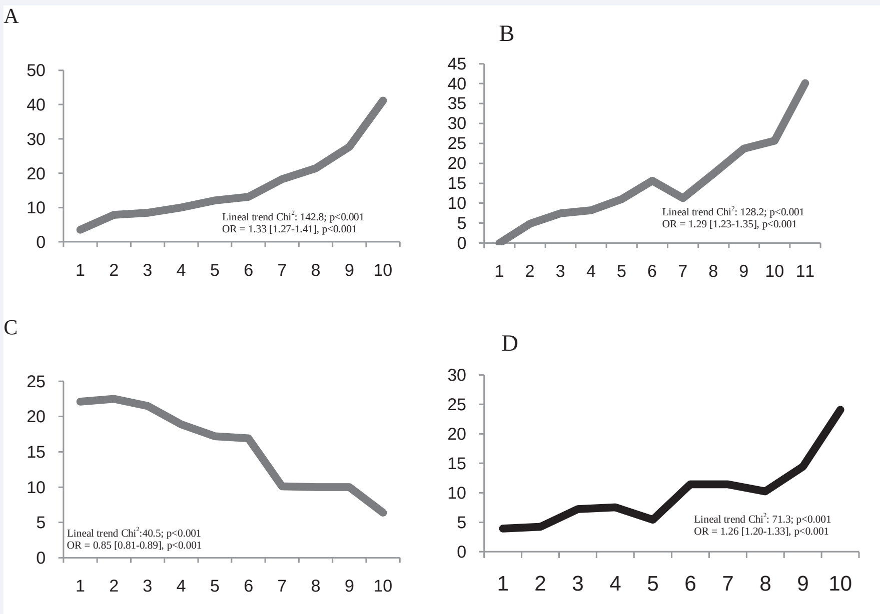

Figure 1 Prevalence (%, Y-axis) of probable OAB by 10%-interval (X-axis) in the General index sleep disturbance score of MOS-sleep scale (graph A) and several domains (sleep disturbance [graph B], adequacy of sleep [graph C] and somnolence [graph D]).
Abbreviations: OAB: Overactive Bladder; OR: Odds Ratio Adjusted by Age and Gender [95% confidence intervals]

by 15% in each 10%-interval (OR: 0.85 [0.81 to 0.89], p<0.001) (Figure 1). After adjusting the summary MOS-S scores for gender, age and their interaction [age; -0.40 (t=-4.4; p<0.001), gender; -0.41 (t=-0.13, p=0.894), gender*age; 0.09 (t=1.61, p=0.107)], the hierarchical linear regression model was calculated and the ROC curve analysis identified the cut-off point that best optimized the pOAB diagnostic classification (Figure 2). The cut-off point that best discriminated pOAB was the summary MOS-S score >31 according to a ROC curve, with AUC = 0.99 (95% CI: 0.986-0.993, p<0.001). Aside from this, as the hierarchical regression model was adjusted for age, gender and their interaction, a subtraction of 0.4 points for each year of age had to be applied to the standardized summary of MOS-S score obtained by correcting the questionnaire (Figure 2). After the cut-off point identification, Table (2) summarizes the diagnostic performance values for the entire sample, and by gender (using the MOS-S cutoff point of >31 for the detection of pOAB). The adjusted MOS-S score of >31 showed an overall sensitivity of 98.5% and a specificity of 90.7% (AUC=0.990 [0.986 to 0.993], p<0.001) to detect pOAB in 72.5% (68.4%-76.3%) of cases (positive post-test probability) and an error probability of 0.4% (0.2%-0.9%) to discard real pOAB (negative post-test probability).In women, the sensitivity of the >31 MOS-S score was higher but its specificity was marginally lower. Overall, it should be noted that the likelihood of a positive ratio was over 10% while the likelihood of a negative ratio was near 0% (0.04% in men and 0.01% in women, respectively). Finally, Figure 3 depicts the probability of correctly classifying patients with pOAB by using different cut-off values of the adjusted general index of sleep disturbance in the MOS-S scale. The >31 MOS-S score represented the cut-off point that obtained more than 90% probabilities of correctly classifying pOAB patients, while the probability of incorrectly classifying a patient as having pOAB falls below 90%.

CONCLUSIONS

The main objective of this post hoc study is to explore the diagnostic performance of the MOS-S scale for the detection of probable OAB syndrome in Spanish population. Our approach

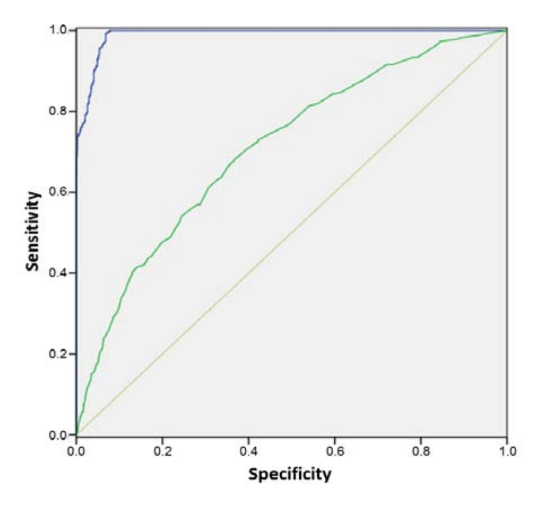

Figure 2 Receiver Operating Characteristic (ROC) curve of the adjusted (blue) and unadjusted (green) General index sleep disturbance score of MOS-sleep scale to detect the best cut-off point differentiating subjects with probable Overactive bladder from the general population.
Footnote: adjusted AUC=0.990 (95% confidence interval; 0.986-0.993), p<0.001 [best cut-off point of total index score > 31 points], unadjusted AUC=0.709 (95% confidence interval; 0.679-0.740), p<0.001 [best cut-off point of total index score > 27 points].

Table 2: Diagnostic test estimators for the General Index score of the MOS Sleep Scale to identify subjects with probable Overactive Bladder in the general population using a best cut-off point of ≥ 31 points.

	Overall sample	**Male**	**Female**
Sensitivity	98.5 (96.5-99.4)	96.0 (91.0-98.3)	99.5 (97.3-99.9)
Specificity	90.7 (89.3-92.0)	95.0 (93.4-96.3)	85.8 (83.2-88.0)
PPV	67.4 (63.1-71.4)	72.9 (65.7-79.1)	64.5 (59.1-69.5)
NPV	99.7 (99.2-99.9)	99.4 (98.7-99.8)	99.8 (99.2-99.9)
False positive rate	9.3 (8.0-10.7)	5.0 (3.7-6.6)	14.2 (12.0-16.8)
False negative rate	1.5 (0.6-3.5)	4.0 (1.7-9.0)	0.5 (0.1-2.7)
Correct classification rate	92.0 (90.7-93.1)	95.2 (93.7-96.3)	88.6 (86.5-90.4)
LR(+)	10.6 (9.2-12.3)	19.4 (14.5-25.8)	7.0 (5.9-8.3)
LR(-)	0.02 (0.01-0.04)	0.04 (0.02-0.10)	0.01 (0.00-0.04)
Observed prevalence	16.3	12.2	20.6
Estimated prevalence	19.9	15.4	23.6
Positive post-test probability	72.5 (68.4-76.3)	77.9 (71.0-83.6)	68.4 (63.1-73.2)
Negative post-test probability	0.4 (0.2-0.9)	0.8 (0.4-1.6)	0.2 (0.0-0.9)

All values expressed in percentage (%).
Abbreviations: PPV: Positive Predictive Value; NPV: Negative Predictive Value; LR: Likelihood Ratio; Observed Prevalence: Pre-Test Probability; Estimated Prevalence: Estimated Pre-Test Probability

was derived from the accumulated evidence of the significant association between sleep disturbances and OAB [6,7], as well as the challenging options for the properly identification and clinical diagnostic of this syndrome [5]. As a consequence that OAB might not being diagnosed during routine clinical practice, any screening tool to identify this syndrome and to facilitate its diagnosis is likely to be welcomed by physicians. It will also improve the implementation and early therapeutic approaches from currently available treatments [6]. It seems also necessary to note here that the MOS-S scale has never previously been used with screening purpose in patients with OAB syndrome. However this potential in the MOS-S scale was expected because nocturia interferes with normal sleep and determines significant reductions in sleep quality, quantity and adequacy [16-19]. Interestingly this study aimed to determine the usefulness of the self-perceived MOS-S scale as a screening tool for pOAB, stating the good quality and feasibility of the proposed scale. Among the values of diagnostic predictability obtained using the observed cut-off point of the MOS-S score, it should be highlighted that all values achieved a high predictability of the model [20]. It is worth distinguishing two important measures of test performance with clinical significance: the positive predictive value (PPV) and the negative predictive value (NPV). The PPV was 72.9% in men and 64.5% in women and shows that more than two thirds of patients with positive test will actually have pOAB. The NPV score in our analysis was 99.7%, demonstrating that more than 99% of

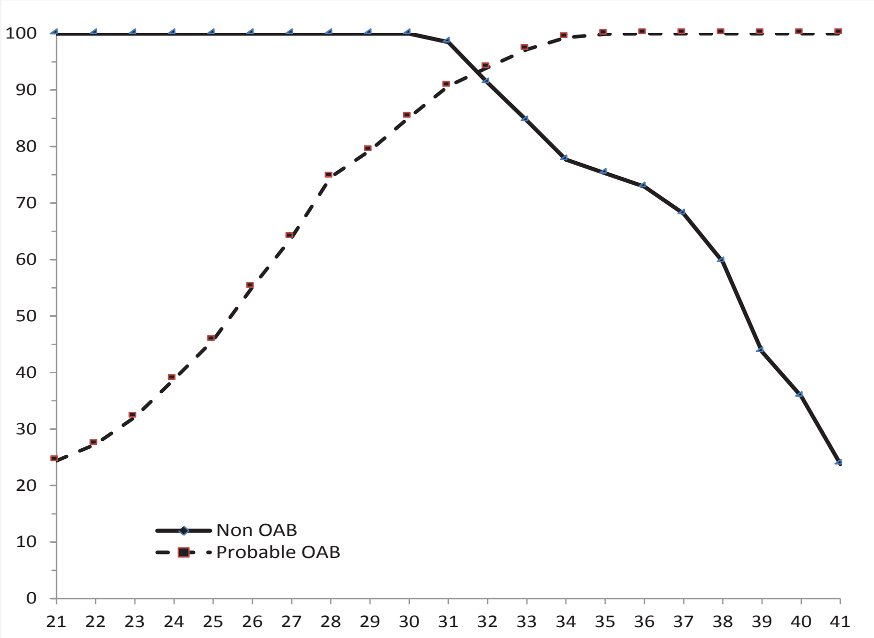

Figure 3 Patients with probable OAB classified correctly (Y-axis, %) by using different cut-off values (X-axis) of the adjusted General index sleep disturbance score of MOS-sleep scale.
Footnote: OAB=Overactive bladder.

patients with a negative test are actually free of the syndrome. These measures are not immutable features of the tool and vary significantly depending on the prevalence of the disease in the observed population. In order to improve this constraint, the likelihood ratio (LR) which is independent of prevalence can be used as an alternative measure with clinical relevance directly at the individual patient level [20]. The 10.6 positive LR in this study shows that it is 10 times more likely that the subject will have a positive test if they have the pOAB syndrome, compared with a person without such a health condition. On the other hand, the 0.02 negative LR of the MOS-S cut-off score for pOAB indicates that it is 50 times less likely that the subject would get a negative test if they had pOAB, compared with a person without the syndrome. Finally, the application of this tool would increase the chance of detecting pOAB in a subject between 18 and 70 years-old with a score of 31 or above in the MOS-S from the estimated prevalence of 19.9% observed in the Spanish general population to 72.5% as observed in this analysis.

Certain limitations of the analysis should also be noted. This was a *posthoc* study based on a data set that was not originally selected for this purpose. In addition, the study sample was drawn from the general population with access to Internet (CAWI method) and did not include population over 70 years. This may have limited the absolute representativeness of pOAB. Also, no patient diary was collected from participants. Finally, it should also be mentioned that pOAB patients were identified using an algorithm that detects the syndrome as probable, but does not result in medical confirmation of OAB. Aside from the above limitations, it should be highlighted that since our study was based on a *posthoc* analysis and the design of the original study included subjects in a random manner the reliability of the obtained model was not compromised by an included sample selected specifically for this objective. Moreover, among the strengths of our study we have to state its large sample size and the fact that the model works through obtaining the prevalence of pOAB in the Spanish general population. The actual prevalence of the syndrome in the population of interest is generally not available in the designs of studies of diagnostic tests and therefore do not allow estimating predictive values and posterior probabilities, unlike what we have achieve with this *post hoc* study. Additionally, these findings offer the opportunity, after a simple trainee process, to healthcare professionals, such as nurses or any type of care managers at primary healthcare system, to actively participating in the managed care of subjects with bladder health conditions aimed to raise promptly the appropriate medical diagnosis, and thus, the adequate treatment of their health problems. Empowering healthcare managers, such as nurses, could improves better management of patient health and it is has previously demonstrated in initiatives others such as cardiovascular diseases in the Leonardo project, [21] or even improves doctor-patient communication in subjects with OAB, particularly female patients when male urologists are their careers, due that the nurse practitioner plays an important role in diagnosing OAB during examination by eliciting specific information about symptoms from patients in their care, and in determining which treatment approaches (i.e., behavioral, pharmacologic, or a combination of both) will help them achieve optimal outcomes [22,23].

In conclusion, using the MOS-Sleep scale to assess the self-perceived quality of sleep could be a useful screening tool for detecting probable OAB, a syndrome that usually remains under-diagnosed and untreated in the general population. Thus, when faced with complaints from patients regarding the quality of sleep, clinicians should explore the patient's bladder health for syndromes such as OAB.

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DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

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Conflict of Interest

Javier Rejas, Sandra Ballestero and Isabel Lizarraga are employees of Pfizer SLU, and Daniel Arumí is employee of Pfizer Inc. Javier Angulo and Francisco Brenes declare that they have no conflict of interest.

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