Validation of a Spanish version of the Sleep-Related Breathing Disorder scale of the Pediatric Sleep Questionnaire in children living in a high-altitude city

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Abstract

Objectives. We aimed to validate a Spanish version of the Sleep-Related Breathing Disorder scale of the Pediatric Sleep Questionnaire (SRBD-PSQ) in children living in a high-altitude Colombian city.

Methods. In a prospective cohort validation study, patients aged between 2 and 18 years who attended the Ear, Nose, and Throat pediatric department of our institution for symptoms related to sleep-related breathing disorders had a baseline visit at enrollment, a second visit the day scheduled for the surgical intervention, and a follow-up visit at least three months after the surgical intervention. In these three visits, we gathered the necessary data for assessing

the criterion validity, construct validity, test–retest reliability, internal consistency, and sensitivity to change of the Spanish version of the SRBD-PSQ.

Results. In total, 121 patients were included in the analyses. The exploratory factor analysis (generalized least squares method, varimax rotation) yielded a four-factor structure, explaining 65.93% of the cumulative variance. The intraclass correlation coefficient (ICC) of the measurements was 0.887 (95% CI: 0.809–0.934), and the Lin concordance correlation coefficient was 0.882 (95% CI, 0.821-0.943). SRBD-PSQ scores at baseline were significantly higher than those obtained after adeno-tonsillectomy surgery (median [IQR] 11.0 [9.0- 14.0] vs. 4.00 [1.50- 7.0]; $p<0.0001$). Cronbach's α was 0.7055 for the questionnaire as a whole.

Conclusions. The Spanish version of the SRBD-PSQ has acceptable construct validity, excellent test-retest reliability and sensitivity to change, and adequate internal consistency-reliability when used in pediatric patients living at high altitude with symptoms related to sleep-related breathing disorders.

Keywords: apnea, child health, polysomnography

Introduction

Obstructive sleep apnea and hypopnea syndrome (OSAHS) is defined as a prolonged complete or partial obstruction of the upper airway that presents intermittently, disturbing the regular ventilation process during sleep.[1-4] OSAHS affects 0.7%–3% of pediatric population,[5] creating a significant burden for patients and their families.[3,6] The most frequent symptoms in children differ from those presented in adults, and therefore it is difficult to identify them. Some of the symptoms include snoring during sleep, noisy breathing, nocturnal awakening, and daytime sleepiness.[5,7] Nevertheless, there are other less-common presentations, with symptoms such as learning disorders or behavioral problems and failure to thrive that make this a challenging diagnosis.[7,8]

In the pediatric population, OSAHS has been identified as a risk factor for learning disabilities,[9] depression,[10] cardiovascular abnormalities, and metabolic derangements.[5]

Even though most of the children diagnosed with OSAHS have an identifiable obstruction, the diagnosis is not always simple given the limited access and high cost of diagnostic tests such as polysomnography (PSG), the gold standard for a diagnosis of OSAHS.[11-13] Therefore, many professionals advocate for the

implementation of questionnaires for screening OSAHS in order to identify patients that would benefit from a PSG.[14-16]

One of the most frequently-used questionnaires for evaluating sleep-related breathing disorders is the Sleep-Related Breathing Disorder scale of the Pediatric Sleep Questionnaire (SRBD-PSQ), developed and validated by Chervin et al.[17] The SRBD-PSQ has been shown to have a strong association with sleep-related breathing disorders, with an area under the ROC = 0.95 ($P<0.0001$). It has been established that values greater than 0.33 suggest this diagnosis (i.e. 33% of the 22 question-items answered positively). Furthermore, this instrument has been shown to have a sensitivity of 85% and a specificity of 87%.[17] This instrument has been used widely, and it has been validated in English,[17] Spanish,[18,19] French,[20] Malayic,[21] Portuguese,[22] Chinese,[23] and Turkish.[24]

Even though the questionnaire has previously been validated in Spanish, showing adequate criterion and construct validity and satisfactory test-retest reliability,[18,19] further validation studies that evaluate other psychometric properties such as sensitivity to change are needed. In addition, the effect of language and cultural background, as well as the impact of altitude, are additional factors that must be taken into account when evaluating its

psychometric properties. Consequently, the aim of the present study was to validate a Spanish version of the SRBD-PSQ in a pediatric Colombian population living in high-altitude settings (2,600 meters above sea level).

Methods

Population and study site

All patients between 2 and 18 years of age that presented at the pediatrics Ear, Nose, and Throat (ENT) pediatric department of the Fundación Hospital La Misericordia from November, 2015 to September, 2017 for symptoms related to sleep-related breathing disorders for whom it was considered necessary to perform a surgical intervention (adeno/amigdalectomy) were deemed eligible to participate in the study. The Fundación Hospital La Misericordia is a tertiary care

university-based children's hospital in the metropolitan area of Bogota, the capital city of Colombia, located at an elevation of about 2,650 m (8,660 ft.) above sea level. Eligible patients were included if the parents provided written informed consent. Patients that did not have a parent or guardian present in all the follow-up visits or those with a guardian not familiar with the sleep patterns of the child were excluded from the analysis. Furthermore, patients with severe comorbidities that could be exacerbating the symptoms, such as those with facial dysmorphism and muscular dystrophy, were also excluded from the analysis.

The Sleep-Related Breathing Disorder scale of the Pediatric Sleep Questionnaire (SRBD-PSQ)

The SRBD-PSQ is composed of 22 items in four domains (snoring, excessive daytime sleepiness, inattention/hyperactivity behavior, and other). Optional responses for each item are as follows: "yes", "no", or "don't know", which are weighted as 1, 0, or missing, respectively, in the same manner as in the original study.[17] The SRBD-PSQ score was calculated by adding up the total count of all positive answers, excluding the missing items, with a higher score indicating greater OSAHS severity. A score greater than 7 (33% of 22 questions answered

positively) was considered to be positive for the presence of sleep-disordered breathing.[17]

The translation of the SRBD-PSQ to Spanish was performed by a certified translator and was evaluated by one author (SMR); then the questionnaire was translated back into English by a different certified translator, who verified that the back-translation had good consistency with the original version. Professor Chervin and his team at the University of Michigan granted us permission to use and validate a Spanish version of the SRBD-PSQ.

Study design and procedures

We conducted a prospective cohort validation study by following a convenience sample of children who fulfilled the above-mentioned eligibility criteria. All study participants had a baseline visit at enrollment, a second visit the day scheduled for the surgical intervention, and a follow-up visit at least three months after the surgical intervention. At the baseline visit, we used standardized forms to collect demographic data of the participants and their parents/caregivers (age, gender, highest level of education) and assessed all the children by using the SRBD-PSQ. In this visit, an overnight PSG was requested for all patients that had not

performed one recently. Fifty patients/parents selected randomly from the total group of participants also completed the SRBD-PSQ the day scheduled for the surgical intervention, 2 to 6 weeks after the first responses, to allow assessment of test-retest reliability. Seventy-three patients/parents selected randomly from the total group of participants also completed the SRBD-PSQ in a follow-up visit 3 to 10 months after the surgical intervention to allow assessment of sensitivity to change.

The study protocol was approved by the hospital's Ethics Committee.

Assessment of the psychometric characteristics of the SRBD-PSQ

To assess the SRBD-PSQ's criterion validity (i.e., the degree to which the measurement correlates with some other measure of the specific construct of OSAHS severity, such as another validated severity instrument or another "gold standard" for the severity of OSAHS), we compared SRBD-PSQ scores at baseline across the three categories of OSAHS severity (mild, moderate, and severe), based on PSG apnea-hypopnea index (AHI). Mild OSAHS was defined as AHI <5 events/hr, moderate OSAHS as AHI >5 and <10 events/hr, and severe OSAHS as AHI >10 events/hr. To evaluate the SRBD-PSQ's construct validity

(i.e. the degree to which elements of an assessment instrument are relevant to and representative of the targeted construct for a particular assessment purpose), we performed an exploratory factor analysis (EFA) with principal component analysis (PCA).

To evaluate the SRBD-PSQ's test-retest reliability (i.e., the consistency of the instrument's results measured on 2 occasions with no change in OSAHS status in between), we compared SRBD-PSQ scores at baseline with those obtained the day scheduled for the surgical intervention. To evaluate the SRBD-PSQ's sensitivity to change (i.e., the ability of an instrument to detect a clinically important change over time), we compared SRBD-PSQ scores at baseline with those obtained at the follow-up visit, at least three months after performing the surgical intervention.

To assess the SRBD-PSQ's internal consistency-reliability (i.e. the degree of correlation between a scale's items), we used the responses given by all the parents/caregivers at baseline.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) or median and interquartile range (IQR), whichever is appropriate. Categorical variables are presented as numbers (percentage).

To assess the SRBD-PSQ's criterion validity, we compared SRBD-PSQ scores at baseline across the three categories of OSAHS severity (mild, moderate, and severe), based on PSG AHI, using the ANOVA test or the Kruskal- Wallis test, as appropriate. To evaluate the SRBD-PSQ's construct validity, an EFA with PCA with Varimax rotation to facilitate the factors' interpretation was carried out, previously using the Kaiser-Meyer-Olkin (KMO) test and the Bartlett test of sphericity for assessing the appropriateness of the sample for the EFA.[25] Horn's parallel analysis and theoretical interpretability were used for deciding how many factors to extract. Horn's parallel analysis adjusts the original eigenvalues for sampling error-induced collinearity among the variables to arrive at adjusted eigenvalues, and analogous to the Kaiser criterion, only factors with adjusted eigenvalues larger than 1 are retained.[26] Items with a uniqueness (1–communality) lower than 0.60 and factor loading (FL) greater 0.30 were selected. To assess the goodness-of-fit of the factor's solution, we evaluated the differences between the correlations in the data and those that the factors imply

(correlation residuals). The SRBD-PSQ's sensitivity to change was determined by using the paired Student's t-test or the Wilcoxon signed-rank test, as appropriate, to compare SRBD-PSQ scores at baseline and at follow-up. Test-retest reliability was assessed with the intraclass correlation coefficient (ICC) and Lin's concordance correlation coefficient and through the construction of a Bland and Altman plot.[27] Internal consistency-reliability was assessed using Cronbach's alpha coefficient.

The data were analyzed with the Stata 11.0 (Stata Corporation, College Station, TX) statistical package.

Results

Patient population

Of the total number of patients who fulfilled the eligibility criteria (n=123), two were excluded because the parents refused to complete the informed consent, so 121 (98.3%) were finally enrolled in the study. The median (IQR) of the age of the 121 patients included in the study was 5.0 (4.0- 7.0) years. The age group distribution was as follows: 49 (40.5%) under 5 years, 66 (54.5%) between 5 and 12 years, and the remaining 6 (5%) older than 12 years. Of the total of patients, 73 (60.3%) were males.

Criterion validity

The SRBD-PSQ scores were not significantly different among patients with severe OSAHS, patients with moderate OSAHS, and patients with mild OSAHS, based on the PSG-AHI obtained at baseline (median [IQR] 12.0 [9.0-15.0], 11.0 [10.0-13.0], and 13.0 [9.25-15.0], respectively; p=0.785)

Construct validity

The mean score for each item ranged from 0.12 to 0.94, with SD of 0.23 to 0.50. The KMO value was 0.657, indicating adequacy for factor analysis, and Bartlett's sphericity value was also statistically significant ($\chi^2 = 706.311$, $p < 0.001$). Before rotation, EFA with PCA revealed eight factors with an eigenvalue greater than 1. After Varimax rotation, Horn's parallel analysis was used for deciding the final number of factors to extract. Of the 22 items, four failed to meet minimum FL of 0.3 or higher, had uniqueness values larger than 0.60, and did not contribute to a simple factor structure, so they were not included in any factor and were deleted (A24, A25, B9, B22). After deleting these items, EFA was performed with the 18 remaining items. The FL was above 0.3 for all items; thus, no additional items were removed. Four potential factors were identified, explaining 65.93% of the cumulative variance. The first factor, which included items related to behavioral alterations, was labeled "behavior", a second factor included items related to snoring and breathing problems, was labeled "breathing", a third factor included items related to problem sleepiness and was labeled "sleepiness", and a fourth factor, comprising items related to observed apnea, nocturnal enuresis, and difficulty getting up in the morning, was labeled "other". The proportion of

correlation residuals with an absolute value higher than 0.05 was 47.40%, suggesting a good model fit. The factor structure is shown in Table 1.

Test-retest reliability

The median (IQR) of the SRBD-PSQ scores at baseline and those on the day of the scheduled surgical intervention were not significantly different (median [IQR] 11.0 [10.0- 15.0] vs. 12.0 [10.0- 15.0]; p=0.210). The ICC of the measurements was 0.887 (95% CI, 0.809-0.934), and the Lin concordance correlation coefficient was 0.882 (95% CI, 0.821-0.943). The Bland and Altman plot shows the agreement of SRBD-PSQ scores between baseline and the second visit. The median difference in the SRBD-PSQ score between the two visits was 0.0, and their corresponding 95% nonparametric limit of agreement was -1.75 to 1.0. One outlier was found, and the points in the plot show a random distribution.

Sensitivity to change

The SRBD-PSQ scores at baseline were significantly higher than those obtained in the follow-up visit after performing the surgical intervention (median [IQR] 11.0 [9.0- 14.0] vs. 4.00 [1.50- 7.0]; p<0.0001). The proportion of children with a score

greater than 7 was significantly greater in the baseline visit as compared to those with a score greater than 7 in the follow-up visit after the surgical intervention (91.7% vs. 18.2%, $p< 0.001$).

Internal consistency

The Cronbach α was 0.7055 for the questionnaire as a whole. For the individual items, this statistic ranged from 0.6597 to 0.7240.

Discussion

The present study showed that the majority of the psychometric characteristics evaluated in a Spanish version of the SRBD-PSQ are appropriate in pediatric patients with symptoms related to sleep-related breathing disorders for whom it is considered necessary to perform an adeno/amigdalectomy. Specifically, it showed acceptable construct validity after performing an EFA with PCA, excellent test-retest reliability when SRBD-PSQ scores at baseline were compared with those obtained the scheduled day for the surgical intervention, excellent sensitivity to change when SRBD-PSQ scores at baseline were compared with those obtained after performing the adeno/amigdalectomy, and adequate internal consistency-reliability. Nevertheless, we could not demonstrate the SRBD-PSQ's criterion validity when SRBD-PSQ scores at baseline were correlated with the three categories of OSAHS severity based on PSG AHI.

The most notable result of the present study is that we have provided further evidence of the psychometric characteristics of a Spanish version of the SRBD-PSQ, therefore contributing to giving confidence to physicians who work in Colombia and probably other similar Spanish-speaking communities for using the questionnaire not only for clinical purposes but also in a research context. The use of a validated instrument for screening (to identify patients that would benefit

with a PSG) and evaluating sleep-related breathing disorders in pediatric patients may greatly contribute to improving clinically important outcomes in these patients, especially in Spanish-speaking low- to middle-income countries (e.g. Colombia), where PSG is not always readily feasible or accessible (acknowledging that PSG remains the current reference standard for diagnosis of sleep-related breathing disorders). Additionally, the present study could also provide meaningful information about SRBD-PSQ performance in populations living at high-altitudes, since Bogota is located 2,600 meters above sea level. Regarding the SRBD-PSQ's construct validity, the factor structure ("breathing", "behavior", "sleepiness", and "other") and factor loadings for the majority of the items are quite similar to those reported in the original questionnaire and in versions of the questionnaire in other languages. In addition, evaluation of the differences between the correlations in the data and those that the factors imply suggests a good model fit for the factor solution. The small differences in factor loadings of some items are expected when validating questionnaires using factor analysis, since not all measurement items capture the underlying constructs effectively or consistently, and also because of linguistic and cultural

specificities.[17] Additionally, these small differences do not affect the factor structure nor the theoretical interoperability of the questionnaire.

Our results with respect to SRBD-PSQ's test-retest reliability are in line with other studies reporting good consistency of the questionnaire results measured on 2 occasions with no change in OSAHS status in between, with time between initial and subsequent questionnaire completion ranging from 14 to 67 days.[17,20-23] Although the time between initial and subsequent questionnaire completion and statistical methods for assessing the SRBD-PSQ's test-retest reliability varies between studies, in conjunction these studies and ours show long-term stability of the questionnaire, with excellent consistency of the instrument's results measured on 2 occasions with no change in OSAHS status in between.

In terms of SRBD-PSQ's internal consistency, similarly to our findings, the Cronbach α values for the individual items or for each domain reported in other studies have ranged from 0.66 to 0.86,[17] from 0.559 to 0.711,[20] from 0.457 to 0.688,[21] from 0.61 to 0.70,[22] from 0.62 to 0.826,[23] and from 0.511 to 0.824.[24] Although to the best of our knowledge no previous studies have evaluated the SRBD-PSQ's sensitivity to change, our findings suggest an adequate ability of the questionnaire to detect a clinically important change over time, because the

SRBD-PSQ scores at baseline were significantly higher than those obtained in the follow-up visit after performing the adeno/amigdalectomy.

Contrary to expectations for our results with respect to the criterion validity of the SRBD-PSQ, the SRBD-PSQ scores were not significantly different among the three categories of OSAHS severity (mild, moderate and severe), based on PSG AHI. We consider that a possible reason for this lack of significant difference could be a reduced spectrum of OSAHS disease severity. This is because although patients were classified as mild, moderate, and severe OSAHS based on PSG AHI, it was considered necessary to perform a surgical intervention (adeno/amigdalectomy) in all of them, suggesting that the majority had moderate to severe OSAHS. It's probable that the inclusion of patients with all the spectrum of OSAHS disease severity, even those without an indication of adeno/amigdalectomy, could make it easier to demonstrate the criterion validity of the SRBD-PSQ.

We acknowledge that at least two limitations could have influenced the results obtained in the present study: First, we used a single-center small convenience sample of patients with symptoms related to sleep-related breathing disorders for whom it was considered necessary to perform an adeno/amigdalectomy. It will be

necessary to conduct additional studies to determine the psychometric characteristics of the Spanish version of the SRBD-PSQ in a large and more representative sample of patients spanning the whole spectrum of OSAHS disease severity. Second, although we performed an EFA with PCA to evaluate the SRBD-PSQ's construct validity, future studies must also test hypothesized structures by performing a confirmatory factor analysis.

In conclusion, findings of the present study suggest that the Spanish version of the SRBD-PSQ has acceptable construct validity, excellent test-retest reliability and sensitivity to change, and adequate internal consistency reliability when used in pediatric patients with symptoms related to sleep-related breathing disorders living at high altitude. Future studies with a larger and more representative sample of patients covering the whole spectrum of OSAHS disease severity are warranted.

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