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Validation of the Greek OSD-6 quality of life questionnaire in children undergoing polysomnography

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ABSTRACT

Objective: OSD-6 is a disease specific questionnaire for pediatric obstructive sleep apnea (OSA). The aims of this study were to validate OSD-6 in Greek language and correlate OSD-6 with polysomnography results.
Study design: Prospective study.
Setting: Tertiary referral center.
Subjects and methods: OSD-6 questionnaire was translated to Greek and back to English. A prospective study was conducted on children undergoing overnight polysomnography due to snoring and disrupted sleep. Test–retest evaluation was carried out. Internal consistency and test–retest reliability were evaluated. Validity was assessed by exploring correlations between OSD-6 scores and apnea–hypopnea index (AHI), and by comparing total scores of OSA and non-OSA groups. Responsiveness was assessed by comparing preoperative to postoperative total scores in OSA children who underwent adenotonsillectomy.
Results: Test–retest evaluation of 91 subjects showed good internal consistency (Cronbach's alpha 0.860 for test and 0.873 for retest) and reliability (Pearson's correlation coefficients between test and retest scores: 0.751–0.546; $p < 0.01$). Total and domains' OSD-6 scores and AHI were significantly correlated (Spearman's correlation coefficients: 0.277–0.630; $p < 0.01$), while children with OSA had higher total OSD-6 score than those without OSA (median (interquartile range): 16 (11) vs. 10 (7), respectively; $p < 0.01$), indicating good validity. Postoperative OSD-6 scores were significantly lower than preoperative (2.84 ± 3.21 vs. 15.42 ± 6.48, respectively; $p < 0.001$), suggesting good responsiveness.
Conclusion: The Greek version of the OSD-6 questionnaire proved to be a valid instrument with satisfactory internal consistency, reliability, validity and responsiveness. Furthermore, in our study OSD-6 was significantly correlated to polysomnography results.

1. Introduction

Pediatric obstructive sleep apnea (OSA) is a relatively frequent disorder that affects 1–3% of children [1–3]. It is characterized by recurring episodes of complete and/or partial upper airway obstruction during sleep, resulting in intermittent hypoxemia and hypercapnia, frequent arousals, and sleep fragmentation, while it differs from adult OSA in physiology, clinical presentation, polysomnographic characteristics, and outcomes. Furthermore, it has unique characteristics not seen in adults, such as hyperactivity, poor performance in school, and growth retardation [1].

The gold standard for diagnosing and quantifying pediatric OSA is overnight polysomnography (PSG). It provides unbiased and objective information on various sleep-related characteristics such as sleep architecture, cardiac and respiratory patterns, and gas exchange. However, PSG is expensive, time-consuming, and frequently unavailable at institutions that treat children with OSA, while it does not predict complications associated with obstructive sleep-disordered breathing such as adverse effects on quality of life (QOL) [1,2].

The obstructive-sleep-disorders-6-survey (OSD-6) is a validated disease-specific instrument designed to assess QOL in children with obstructive sleep disorders before and after surgical treatment. It is composed of six items, which reflect the following: (1) physical suffering, (2) sleep disturbance, (3) speech and swallowing difficulties, (4) emotional distress, (5) activity limitation, and (6) level of concern of the caregiver associated with the

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patient's illness and related symptoms. Parents rate each item on a scale from 0 to 6 based on how they feel the symptoms affect their child [3–6]. Even though it has been shown to be of use as an evaluative measure, showing changes in QOL before and after adenotonsillectomy [3–6], it has not been validated against PSG so far (PubMed search).

The first objective of the present study was to translate, adapt and validate OSD-6 questionnaire in Greek, while the second objective was to explore potential correlations of OSD-6 scores with PSG results.

2. Material and methods

2.1. Translation of OSD-6 questionnaire

Validation of the Greek questionnaire included translation of the OSD-6 questionnaire from English to Greek by two independent native Greek translators and retranslation back from Greek to English by two other native English translators [7,8].

2.2. Study participants and setting

A prospective instrument validation study was conducted on children undergoing overnight PSG in University Hospital of Larissa – Greece. Only children aged 2–18 years old with a history of snoring and disrupted sleep for at least 3 months, whose caregivers were able to read and understand Greek, were included in the study. The study was approved by the University Hospital of Larissa Review Board.

The exclusion criteria were: (1) prior tonsil, adenoid, or pharyngeal surgery, (2) down or other syndrome involving the head and neck, (3) neuromuscular disorders, (4) cleft palate or previous pharyngeal surgery, (5) known cognitive deficit or mental retardation, (6) known psychiatric disorder, and (7) inability of caregiver to read and understand Greek.

Participants underwent overnight PSG at the Sleep Disorders Laboratory. The following signals were recorded: electroencephalogram (C3/M2, F4/M1, O1/M2, O2/M1); right and left oculogram; submental and tibial electromyogram; body position; electrocardiogram; thoracic and abdominal wall motion; oronasal airflow (three-pronged thermistor and nasal pressure transducer); and oxygen saturation of hemoglobin (SpO2). Arousals, sleep stages, and respiratory events were scored and polysomnography indices were defined according to the American Academy of Sleep Medicine Manual for both children and adolescents [9]. Apnea–hypopnea index (AHI) was calculated as the mean number of obstructive and mixed apneas and hypopneas per hour of total sleep time. In our study, pediatric OSA was defined as AHI ≥ 1 episode/h [10]. Therefore, OSA and non-OSA groups consisted of children with AHI ≥ 1 and AHI < 1, respectively.

Since there is no widely accepted theoretical basis for determining sample size or power calculation in questionnaires psychometric validation [11], we have used the general rule of thumb for our sample size calculation. According to this rule, the minimum recommended participants size is between 5 and 10 times the number of questionnaire items [11]. In our study, we have considered the 5–1 as the minimum ratio of participants to items for every group and subgroup we have analyzed.

2.3. Test–retest study

The test–retest reliability was carried out by asking caregivers to complete the OSD-6 questionnaire at their first visit to the outpatient clinic (test) and in the evening immediately prior to PSG (retest).

2.4. Preoperative–postoperative evaluation

In the subgroup of children with OSA who underwent surgery, further evaluation obtained with the Greek OSD-6 questionnaire the day before surgery and 3 months postoperatively.

2.5. Data analysis

Internal consistency of the Greek OSD-6 questionnaire was evaluated by applying Cronbach's alpha test with a minimum acceptable value of 0.7.

Test–retest reliability was assessed by exploring the correlation between OSD-6 scores (total as well as score of each item) during the first visit (test) and those in the evening prior to PSG (retest) by the Pearson's correlation coefficient.

The responsiveness of the questionnaire was assessed by comparing OSD-6 scores before and after surgery using paired *t*-test.

The validity of the questionnaire against PSG was assessed by examining the correlation between AHI and OSD-6 scores prior to PSG (Spearman's correlation coefficient), and by comparing total scores between non-OSA and OSA groups by applying the Mann–Whitney *U*-test.

Data analysis was performed using the SPSS 20 statistical software (IBM, Chicago, IL, USA). Values of $p < 0.05$ were considered as significant results.

3. Results

Appendix shows the Greek translation of OSD-6 questionnaire.

Ninety-four (94) children followed at the ENT department underwent overnight PSG from January 2012 till December 2013. The questionnaire for the test–retest evaluation was fully completed for 91 children, (38.46% female; mean age of 7.04 (±2.53); range 3–15 years). Fifty (50) of 91 children (46% female; mean age 6.68 (±2.36); range 3–12 years) recruited in the study

Table 1
Test–retest reliability for OSD-6 questionnaires completed during the initial clinic visit (test) and prior to polysomnography (retest) and validity of the retest OSD-6 scores in relation to the apnea–hypopnea index (AHI) are shown.

	Test–retest reliability	Validity in relation to AHI
	Pearson's correlation coefficients between scores of test and retest OSD-6 questionnaires	Spearman's correlation coefficients between retest scores and AHI
Total OSD-6 score	0.708[a]	0.630[a]
1. Physical suffering	0.606[a]	0.612[a]
2. Sleep disturbance	0.650[a]	0.624[a]
3. Speech or swallowing problems	0.700[a]	0.460[a]
4. Emotional distress	0.621[a]	0.277[a]
5. Activity limitations	0.751[a]	0.470[a]
6. Caregiver concerns	0.546[a]	0.520[a]

[a] Significant at the 0.01 level (2-tailed).