International Journal of Pediatric Otorhinolaryngology 129 (2020) 109727

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl

Linguistic adaptation and validation of Italian version of OSA-18, a quality of life questionnaire for evaluation of children with obstructive sleep apnea-hypopnea syndrome (OSAS)

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ARTICLE INFO

Keywords:
OSA-18
Pediatric obstructive sleep apnea
OSA
Overnight oximetry
QOL
Italian

1. Introduction

Obstructive Sleep Apnea Syndrome (OSAS) is defined as a respiratory sleep disorder characterized by prolonged episodes of partial obstruction and/or complete intermittent obstruction of the upper airways disturbing nighttime ventilation and disrupting the normal pattern of sleep [1].

The prevalence of OSAS is 1–3% in the pediatric population [1]. The hypertrophy of adenoids and tonsils is reported to be the main risk factor for OSAS in children. Other risk factors are an increased Body Mass Index (BMI) [2] and craniofacial anomalies [3], including a high and narrow palatine vault, retruded mandible and reduced dental arches' diameters, associated or not with the presence of a dental lateral and/or posterior crossbite [4–6].

Symptoms of pediatric OSAS include poor concentration skills, daytime sleepiness, irritability, relationship difficulties, nocturnal enuresis, awakening headaches, restless sleep [6,7]. Pediatric OSAS has various negative health and behavioral consequences, including cardiovascular, metabolic and neurological diseases [8–10]. Furthermore, these complications can influence the general health and quality of life of children affected [7,9].

The gold standard for the diagnosis of OSAS is nocturnal polysomnography (PSG). PSG, however, has high costs and its practical feasibility is limited due to poor compliance of children [11,12]. As an alternative to PSG, the use of nocturnal oximetry has been proposed [11–14] and the McGill Oximetry Scoring system (MOS) was introduced to estimate the severity of sleep breathing disorder [12,15]:

- McGill Oximetry score of 1 (normal or inconclusive oximetry) corresponds a baseline SpO2 > 95% with fewer than three clusters of desaturation events [12,15];
- McGill Oximetry score of 2 (mildly abnormal oximetry) refers to at least three clusters of desaturation events and three or moreSpO2 drops to less than 90% but not less than 85% [12,15];

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https://doi.org/10.1016/j.ijporl.2019.109727
Received 22 July 2019; Received in revised form 3 October 2019; Accepted 12 October 2019
Available online 17 October 2019

- McGill Oximetry score of 3 (moderately abnormal oximetry) corresponded to at least three clusters of desaturation events and more than three SpO2 drops to less than 85% but not less than 80% [12,15];
- McGill Oximetry score of 4 (severely abnormal oximetry) referred to at least three clusters of desaturation events and more than three SpO2 drops to less than 80% [12,15].

Therefore, the use of pulse oximetry is acceptable when PSG is not available and has already been used in questionnaire validation studies [16].

Nevertheless, oximetry score of 1 requires further investigation by mean of PSG, given the low negative predictive value of oximetry for the presence of OSA [12,15,16].

The impact of OSAS on the quality of life of the child and the family has aroused increasing interest in the scientific community over the last decades and many disease-specific QOL surveys have been proposed for evaluation of OSAS children. The OSA-18 questionnaire by Franco et al. [17,18] is the most widely used QOL survey for pediatric OSA, and has been validated as an evaluative and discriminative instrument. The OSA-18 questionnaire is completed by the child's caregivers and consists of 18 questions covering five areas of interest: 1) sleep disorders, 2) physical symptoms, 3) emotional symptoms, 4) daytime behavior and 5) parental concern. The caregiver responds by assigning an evaluation from 1 to 7, where "1″ is equivalent to "never" and "7″ is equivalent to "always". The minimum score is therefore 18, the maximum score is 126. The OSA-18 is useful to classify the impact of the disease on the quality of life: on average by score < 60, moderated by score between 60 and 80, severe for a score greater than 80. The OSA-18 questionnaire's questions are simple and immediate, which makes it suitable for use in the most varied clinical and research settings in the field [7,17].

The questionnaire OSA-18 was designed for an English-speaking population and the use in non-English-speaking countries presupposes the translation and validation of the same in the language of target population [18–21]. To date, there is no validated Italian version of the OSA-18 questionnaire. The aims of this study are to translate and validate in Italian language the OSA-18 questionnaire in children and to investigate the correlations between the score of the OSA-18 questionnaire and the levels of nocturnal oxygen saturation.

2. Materials and methods

2.1. Translation of OSA-18 questionnaire

The validation process of the Italian version of the OSA-18 questionnaire consists essentially of two phases: the first phase is the translation into Italian of the original in English and then reverse translation and verification, the second phase consists in measuring the psychometric properties, validity and reliability of the translation obtained.

2.2. First phase: translation into Italian of OSA-18 questionnaire

Two specialists in orthodontics and one bilingual expert whose mother tongue is Italian independently translated the questionnaire from English to Italian. The 3 versions were unified by consensus between the translator and the researchers. A bilingual translator, English mother tongue, back-translated this final version. After back-translation, a committee of three orthodontists and one expert translator, Italian mother tongue, adapted the Italian questionnaire in order to improve the semantic equivalence of meaning between the two English versions. After these phases, the first version of the Italian OSA-18 questionnaire was created. This version was initially pilot tested on a convenience sample of 15 volunteers chosen among the parents and caregivers of children attending their first dental check up at the Unit of Odontology of Bambino Gesù Children's and Research Hospital (Rome) to determine if the questions were clearly understood. The pilot test was performed by a single investigator (EA), through a direct interview, to assess possible difficulties in understanding the questionnaire. After some aspects were modified to facilitate comprehension, the translation into Italian was finalized (Table A).

2.3. Second phase: Questionnaire validation

2.3.1. Study participants and setting

A prospective instrument validation study was conducted in children from 3 to 12 years old referred to the Ear Nose and Throat (ENT) or Dental Unit of the Bambino Gesù Children's Hospital in Palidoro, Rome (Italy) for suspected OSAS.

The exclusion criteria were caregivers' inability to read and understand Italian, syndromes or congenital defects, systemic diseases that can alter the normal growth pattern, other diseases that may affect the quality of life of the patients and/or their families, prior tonsillar, adenoidal or pharyngeal surgery, and/or refusal to participate in the study.

All the children included in the study underwent overnight oximetry. Overnight oximetry recordings were evaluated according to Nixon et col [12,14]. and the McGill Oximetry Score (MOS) was used to assess presence of OSAS and to describe levels of nocturnal oxygen saturation. All patients included in the study were divided in 1) Group A (MOS = 1) and 2) Group B (MOS > 1). Group B was additionally divided in three subgroups according to MOS score; Group B.2 (MOS = 2), Group B.3 (MOS = 3) and Group B.4 (MOS = 4).

Patients with MOS = 1, whose clinical conditions suggested second level exams to exclude the presence of OSA, underwent PSG to proceed to the most indicated therapy. Results from second level exams did not influence patients' allocation, since reallocation would have created confusion in the definition of respiratory parameters. Therefore, all patients with MOS = 1 included into the study stayed in Group A with no regard to results of PSG, if any.

All the caregivers of the participants in the study completed the Italian version of the OSA-18 questionnaire obtained from the translation and adaptation process from the original English version during the first visit to the ENT and/or Dental Unit. Furthermore, the questionnaire was completed again at one month after the first visit, for retest evaluation.

Caregivers of the Group B who underwent surgery were asked to complete the OSA-18 questionnaire again at 1–3 months after surgery to evaluate responsiveness.

The Ethical Committee of the Bambino Gesù Children's and Research Hospital has approved the study and caregivers signed an informed consent for treatment of personal data and publication of the results of the study.

2.3.2. Sample size and data analysis

50 subjects were intended to be included in the sample, net of possible drop-outs. With an alpha level = 0.05 we have a 90% study power. The expected effect is a correlation measured with the overall Cronbach's alpha between 0.80 and 0.90. Cronbach α (alpha) was used as a measure of the internal consistency of the Italian OSA-18 in addition to the correlation between the total score of the Italian OSA-18 and its subdomains.

Clinical and demographic characteristics of all the patients enrolled were described.

The Shapiro–Wilk test was applied to assess the normality of the distribution of each variable. Comparisons among proportion were performed using the Chi-squared test or Fisher's exact test for categorical variables as appropriate. Medians were compared with the Wilcoxon or Mann-Whitney rank-sum test.

It was calculated descriptive statistics and report median with IQR and ranges or mean ± SDs as appropriate for the data distribution. We

Table 1
Test–retest reliability for OSA-18 questionnaires and validity of the OSA-18 scores in relation to the Mc Gill score (MOS) are shown.

	Test–retest reliability	Validity in relation to MOS	Responsiveness in OSA-18 scores following adenotonsillectomy
	Pearson's correlation coefficients between scores of test and retest OSA-18 questionnaires	Spearman's correlation coefficients between retest scores and MOS	Paired *t*-test *P*
OSA-18 total score	0.5763[a]	0.5399[a]	< 0.001
1. Loud snoring	0.4296[a]	0.5056[a]	< 0.001
2. Breath holding/pauses	0.4809[a]	0.6667[a]	< 0.001
3. Choking or gasping	0.4736[a]	0.4307[a]	< 0.001
4. Fragmented sleep	0.5049[a]	0.5741[a]	< 0.001
5. Mouth breathing	0.2788[a]	0.5914[a]	< 0.001
6. Frequent colds or upper respiratory tract infections	0.5466[a]	0.2068	< 0.001
7. Rhinorrhea	0.2754[a]	0.1242	< 0.001
8. Dysphagia	0.5236[a]	0.5596[a]	< 0.001
9. Mood swings or tantrums	0.5537[a]	0.2406	< 0.001
10. Aggression/hyperactivity	0.4636[a]	0.2168	0.0018
11. Discipline problems	0.4488[a]	0.1139	0.0019
12. Daytime drowsiness	0.5969[a]	0.3268[a]	< 0.001
13. Poor attention span	0.3960[a]	0.0676	< 0.001
14. Difficulty awakening	0.5464[a]	0.1407	< 0.001
15. Caregiver worried over child health	0.4430[a]	0.4683[a]	< 0.001
16. Caregiver concerned the child does not get enough air	0.4796[a]	0.5427[a]	< 0.001
17. Caregiver missed activities	0.4972[a]	0.3867[a]	< 0.001
18. Caregiver frustration	0.5169[a]	0.2113	< 0.001

[a] Correlation is significant at a level of 0.05.

report percentages for categorical or dichotomous variables.

A concordance analysis was performed to evaluate the reliability of the test-retest calculating Pearson's correlation between scores of test and retest OSA-18 questionnaires and Spearman's correlation coefficients between retest scores and McGill. Kruskal- Wallis equality-of-populations rank test was used to compare continuous values of OSA-18 questionnaires at one month (retest) by McGill score.

The responsiveness of the questionnaire was assessed by comparing the OSA-18 scores before and after surgery for the subgroup of children who underwent adenotonsillectomy by using paired *t*-test.

All statistical analyses were performed using STATA, Statistical Software: Release 13. College Station, Tx: StataCorp 2013.

3. Results

79 children underwent overnight oximetry from May 2017 till June 2018. 14 patients were excluded because they did not meet the inclusion criteria. 65 patients were recruited in the study and completed the questionnaire at the first visit. 55 out of 65 children fully completed the initial questionnaire and the retest evaluation at one month and were included in the final sample (49% male, 51% female) with a mean age of 5 (SD) ± 1.4 years, IQR 4.1–5.5, range 3.1–10.1 years. 31 (56.4%) of 55 children recruited in the study were assigned to the Group B (MOS > 1) and surgical therapy was recommended. 24 (43.6%) of 55 children were assigned to the Group A (MOS = 1) with an indication for no-treatment and/or medical therapy and follow-up.

All correlations between test and retest evaluation were significant for the total score (P < 0.01) and for all subscales and items (Table 1). MOS and OSA-18 retest total scores were significantly correlated (P < 0.01), when considered individually not all items were significantly correlated (Table 1). Cronbach's alpha was 0.912 and 0.933 respectively at T0 and at retest examination.

Children with OSAS had higher total OSA-18 score than participants without a conclusive diagnosis of OSAS. In the Group A, median OSA-18 score was 43, IQR (32–62). Group B was divided in three subgroups accordingly to MOS score; B.2 (MOS = 2) consisted of 15 children, B.3 (MOS = 3) and group B.4 (MOS = 4) consisted of 8 children each. For the three subgroups, median OSA-18 scores were 69, IQR (52–93), Range (38–120), 71, IQR (60–83), Range (37–112), 82, IQR (75–87), Range (68–99) respectively in the B.2, B.3 and B.4 subgroups. All these three subgroups differed significantly (p < 0.05) from the Group A regarding the OSA-18 score; there were no significant differences between Group B subgroups.

The sensitivity of OSA-18 to detect OSAS, as diagnosed by oximetry, was 67.7%, while its specificity was 75.0% (Table 2).

Considering the Group B, based on the OSA-18 total score, the impact of OSAS on quality of life (QOL) was average in 8 cases (6 children from Group B.2, 2 children from Group B.3), moderate in 9 cases (3 children from Group B.2, 3 from Group B.3, 3 from Group B.4, severe in

Table 2
True positive/negative and false positive/negative total OSA-18 score in OSA (MOS > 1) and non-OSA (MOS < 1) groups as defined by overnight oximetry.

Total OSA-18 score	MOS < 1	MOS > 1	Total
Negative for OSA (< 60)	18	10	28
Positive for OSA (≥60)	6	21	27
Total	24	31	55
Pearson chi2 (1) = 9.8883 Pr = 0.002			

Table 3
The impact of OSAS on the quality of life of 31 children (OSA group).

Osa 18 total score	Impact on quality of life (QOL)	Frequency (n)
< 60	Average	7
[60–80]	Moderate	12
≥80	Severe	14

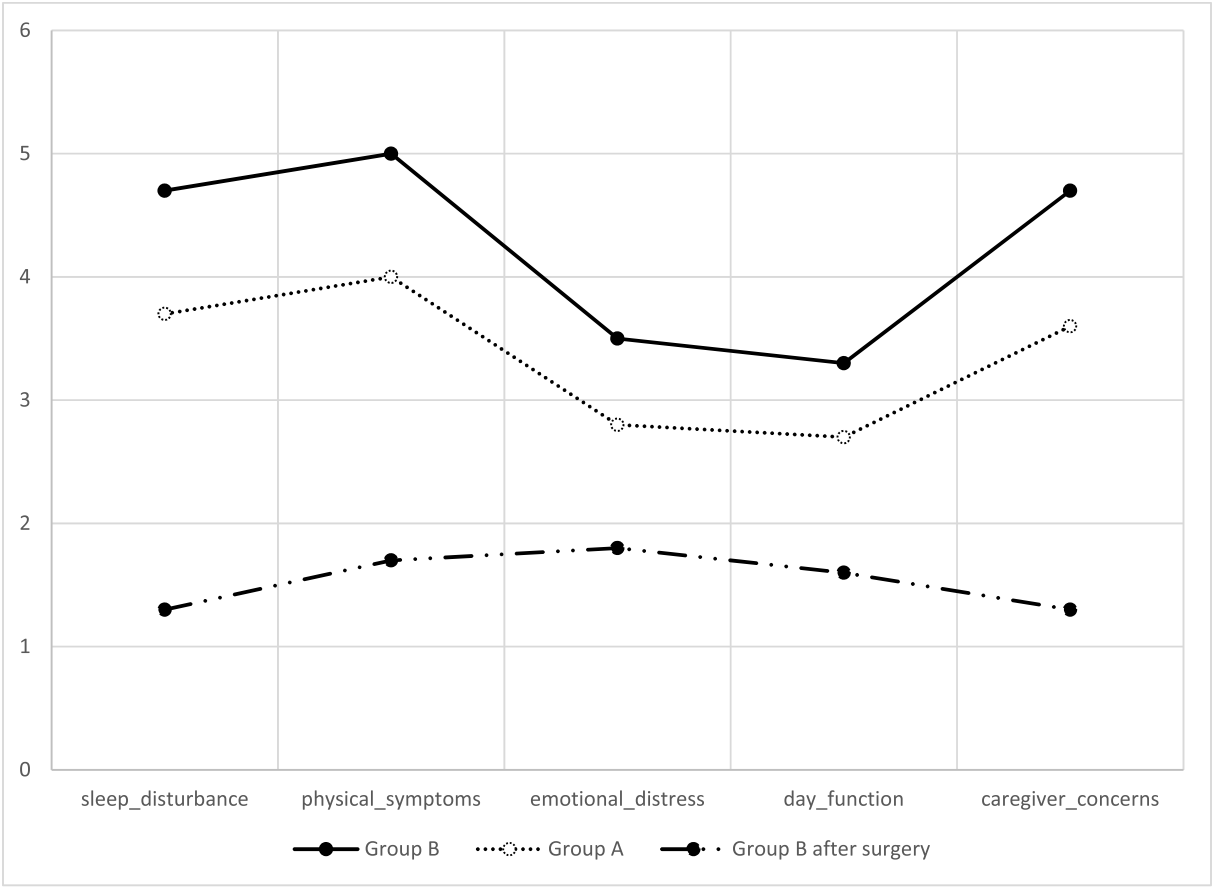

Fig. 1. Mean OSA-18 scores for subscales in Group A, Group B, and Group B after adenotonsillectomy.

14 cases (6 children from Group B.2, 3 from Group B.3, 5 from Group B.4) (Table 3).

All patients in the Group B received a surgical indication for adenotonsillectomy. Six patients were lost at follow up in the Group B and did not follow the surgical indication and/or did not complete the OSA-18 questionnaire at T1. 25 patients out of 31 underwent adenotonsillectomy and their caregivers completed the Italian version of OSA-18 between 1 and 3 months after surgery. After surgery (T1), OSA-18 scores decreased significantly compared to preoperatively scores (T0) indicating good responsiveness. The mean OSA-18 score at T1 was 26.64 ± 6.48 vs the mean OSA-18 score at retest evaluation (T0 -1 month) 76.36 ± 21.89, $P < 0.001$ (Table 1). Furthermore, significant differences were demonstrated in scores for all OSA-18 subscales Fig. 1.

4. Discussion

QOL is increasingly recognized as an important health outcome measure in clinical medicine. Many disease-specific QOL surveys have been proposed for evaluation of OSAS children and of the impact of OSAS on the QOL. The OSA-18 questionnaire by Franco et al. [17,18] is the most widely used QOL survey for pediatric OSA, and is validated in many languages.

Our study aimed at translation and validation of Italian OSA-18 questionnaire.

During the translation and cross-cultural adaptation, which was the first step of the validation process, there was no need to apply substantial modifications to the first-structured version of the Italian OSA-18 questionnaire probably due to a substantial affinity between the European sociocultural contexts where the questionnaires were developed and tested. The only change needed was in regard to the item n.17 where we had to state clearly the object of the question given in the English version by a pronoun which is not uniquely translated into Italian.

The final version obtained from the first phase was then tested through our study's second phase.

The internal consistency of the Italian translation of OSA-18 was analyzed in our study. Internal consistency measures how well the scores for the individual items of the instrument correlate with each other. In our study, Cronbach's alpha was 0.912 and 0.933 respectively at T0 and at retest examination, suggesting good internal consistency of the Italian OSA-18. Test–retest reliability reflects stability of calculated scores with repeated testing and can be evaluated by correlating initial test and subsequent retest scores. In our study, correlations of test–retest evaluation were significant for total OSA-18 score as well as for scores assigned to all subscales and items. Validity is the extent to which a test accurately measures what it is supposed to measure [17,18]. In our field, it is the ability of an instrument to distinguish between patient groups who have or do not have the disease being studied. In our study, validity of the OSA-18 was assessed by exploring potential correlations between questionnaire's results and MOS scores and by assessing the sensitivity and specificity of OSA-18 for detecting OSAS. The results of the study showed that total OSA-18 scores was significantly correlated with a MOS > 1, indicating presence of OSAS. When considering the five subscales and single items' scores (Table 1), correlations were significant for: all items of subscale 1 “sleep disorders”, items 5 and 8 of subscale 2 “physical symptoms”, item 12 of subscale 4 “daytime behavior”, all items of subscale 5 “parental concern” except item 18 regarding parental frustration. Correlations were not significant for subscales 3 “emotional symptoms”, nevertheless poor correlation in subscales 3 and 4 is reported from Franco in its original article as well [17,18]. Lack of statistical significance for some items could be due to some limitation of our study. First, previous studies

used PSG instead of oximetry for instrumental evaluation of OSAS; it is possible that for some extent a variation in results is related to the use of oximetry and MOS. In addition, parents were blinded in respect to oximetry results at the time of the first submission but were aware of oximetry results when completing the retest. The Italian version of the questionnaire demonstrated a sensitivity of 67.7% and a specificity of 75%, the original version of OSA-18 has a sensitivity of 40% and a specificity of 73% when compared to diagnosis obtained from nocturnal pulse oximetry [8]. Franco [17] suggested that a total OSA-18 score greater than 60 indicates a negative impact of child's respiratory conditions on his/her quality of life and is suggestive of OSA. In our study the total OSA-18 cut-off score was also set to 60. All subgroups of Group B had significantly higher OSA-18 score than children in Group A; nevertheless, these subgroups did not show a significant difference when compared to each other. This finding is equivalent to those of other studies [17,18] were the OSA-18 was not efficient in identifying different levels of severity of OSAS, where PSG was used as diagnostic tool. However, since our stratification is based on MOS, the results may not be comparable. Two additional considerations come out from these results; 1) OSA has a wide range of impaction on QOL, which is independent from pulse oximetry scores, 2) caregivers concerns may act as a bias in reporting patients' QOL. The sensitivity of OSA-18 to detect OSA, as diagnosed by oximetry, was 67.7% which confirms the poor validity of the questionnaire as a diagnostic instrument compared to other tools (i.e. oximetry, PSG) [17,18]. On the other hand, during clinical examination, reported symptoms and perceived QOL should be taken in greater consideration when evaluating the disease's impact on patients and families. More scientific research is needed in the area of pediatric OSAS to determine homogenous clinical and instrumental diagnostic criteria and to correlate survey data with quality of life, clinical parameters and instrumental results. In addition, a self-reported QOL instrument is necessary to avoid caregivers' bias in completing the proposed surveys. Since the concept of health in children and teenagers includes also their ability to perform age-appropriate activities, age adapted instruments for QOL evaluation should be created in order to let the pediatric patient express personal opinion and direct perception of QOL.

5. Conclusion

The OSA-18 questionnaire is a quick, easy-to-use instrument used to determine the quality of life of subjects with OSAS. This study shows that the Italian OSA-18 questionnaire has satisfactory internal consistency and validity, is equivalent to the original English version and is suitable for use with Italian-speaking patients.

Declaration of competing interest

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

We further confirm that any aspect of the work covered in this manuscript has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript. We understand that the Corresponding Author (Angela Galeotti) is the sole contact for the Editorial process (including Editorial Manager and direct communications with the office). She is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs. We confirm that we have provided a current, correct email address which is accessible by the Corresponding Author and which has been configured to accept email from (angela.galeotti@opbg.net).

Acknowledgements

The authors are grateful to the Departments of ENT and Odontology of the Bambino Gesù Children's and Research Hospital for their continuous help and constant support.

Appendix

Table A
The Italian version of OSA-18 questionnaire

Nome del Paziente:	Data di Nascita:	Roma, lì						
Per ogni domanda indichi il punteggio che meglio descrive i sintomi o le situazioni verificatesi nelle scorse 4 settimane. Utilizzi un solo numero per ciascuna domanda. Grazie								
Disturbi durante il sonno								
Durante le scorse 4 settimane, quanto spesso suo figlio ha …								
russato forte?		1	2	3	4	5	6	7
trattenuto il respiro o avuto pause mentre respirava di notte?		1	2	3	4	5	6	7
avuto la sensazione di soffocamento o fatto rumori ansimanti mentre dormiva?		1	2	3	4	5	6	7
avuto un sonno disturbato o frequenti risvegli durante il sonno?		1	2	3	4	5	6	7
Sintomi fisici								
Durante le scorse 4 settimane, quanto spesso suo figlio ha …								
respirato a bocca aperta a causa di un'ostruzione nasale?		1	2	3	4	5	6	7
avuto frequenti raffreddori o infezioni alle vie respiratorie?		1	2	3	4	5	6	7
avuto secrezioni nasali?		1	2	3	4	5	6	7
avuto difficoltà nella deglutizione?		1	2	3	4	5	6	7
Sintomi emotivi								
Durante le scorse 4 settimane quanto spesso suo figlio ha avuto …								
sbalzi d'umore o crisi di rabbia?		1	2	3	4	5	6	7
comportamenti aggressivi o iperattivi?		1	2	3	4	5	6	7
problemi di disciplina?		1	2	3	4	5	6	7

(*continued on next page*)

Table A (*continued*)

Nome del Paziente:	Data di Nascita:	Roma, lì						
Comportamento diurno								
Durante le scorse 4 settimane quanto spesso suo figlio ha avuto …								
eccessiva sonnolenza diurna?		1	2	3	4	5	6	7
difficoltà di attenzione o concentrazione?		1	2	3	4	5	6	7
difficoltà nel svegliarsi al mattino?		1	2	3	4	5	6	7
Preoccupazione dei genitori								
Durante le scorse 4 settimane quanto spesso i problemi di suo figlio sopra decritti hanno …								
determinato in lei preoccupazione sulla salute generale di suo figlio?		1	2	3	4	5	6	7
determinato in lei preoccupazione che suo figlio non respirasse bene?		1	2	3	4	5	6	7
interferito nello svolgimento delle sue attività quotidiane di genitore?		1	2	3	4	5	6	7
determinato in lei un senso di frustrazione?		1	2	3	4	5	6	7

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