Translation and validation study of obstructive sleep apnoea (OSA-18) questionnaire into Bahasa Malaysia (MALAY OSA-18)

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ABSTRACT

Introduction: According to the American Academy of Sleep Medicine, obstructive sleep apnoea (OSA) is sleep-related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe. The OSA-18 questionnaire is a short and self-administered questionnaire to assess paediatric patients' symptoms and quality of life with obstructive sleep apnoea.

Materials and Methods: This cross-sectional study is conducted at the Otorhinolaryngology-Head and Neck Surgery (ORL-HNS) clinic of Hospital Universiti Sains Malaysia. The forward and backward translation of the OSA-18 questionnaire into the Malay language (Malay OSA-18) was performed and tested for content and face validity. The questionnaire's internal validity and reliability were tested using Pearson's correlation, Cronbach α and inter-reliability coefficient tests. The psychometric properties (validity, reliability and reproducibility) were assessed.

Results: We observed 84 patients ranging from six months up to 12 years of age. The mean age was 8 years old, and 63.1% were male patients. Among the samples, 96.4% presented with palatine tonsillar enlargement, and 84.5% presented with adenoid tonsillar enlargement. Based on the questionnaire the patient's caregiver answered, Pearson's correlation demonstrated that all the symptom scales correlate and measure the same things. The Cronbach's α coefficient value for each symptom scale was acceptable, within 0.6-0.8. The total Cronbach's α coefficient value was 0.89. The test-retest evaluation was excellent, with the value of intraclass correlation (ICC) more than 0.90.

Conclusion: The Malay version of the OSA-18 questionnaire is equivalent to the original English version. It is an effective tool to assess the paediatric OSA patient's symptoms and quality of life based on the obtained validity, reliability and reproducibility values. Therefore, it is recommended to be a screening tool in daily practice.

KEYWORDS:

Obstructive sleep apnoea, paediatrics, OSA-18 questionnaire, Malay language, validity, reliability

INTRODUCTION

Obstructive sleep apnoea (OSA) is a spectrum of sleep-related breathing disorders that involves a decrease or complete pause of airflow despite an ongoing respiratory effort. It occurs when the muscles relax during sleep, causing soft tissue in the back of the throat to collapse and block the upper airway. This leads to partial reductions (hypopneas) and complete pauses (apnoea) in breathing that last at least 10 seconds during sleep. Most pauses last between 10 and 30 seconds, but some may persist for one minute or longer.

The brain responds to the lack of oxygen by alerting the body, causing a brief arousal from sleep that restores normal breathing. This can lead to abrupt reductions in blood oxygen saturation, with oxygen levels falling as much as 40% or more in severe cases. This pattern can occur hundreds of times in one night. The result is a fragmented sleep quality that often produces excessive daytime sleepiness. Most people with OSA snore loudly and frequently, with periods of silence when airflow is reduced or blocked. They then make choking, snorting or gasping sounds when their airway reopens.¹

OSA is a common chronic illness with a consequence in neurobehavior, cardiopulmonary, metabolic systems and somatic growth. It is highly plausible that common pathogenic mechanisms are triggered by the interactions of intermittent hypoxia and hypercapnia, intrathoracic pressure swings and episodic arousal. Clinical criteria usually diagnose OSA. Although polysomnography (PSG) is considered the gold standard for assessing the severity of OSA and treatment outcomes, clinical evaluations may not necessarily reflect the impact of the disease on a patient's quality of life (QOL). Based on patient reports, health-related quality of life (HRQOL) instruments usually assesses the patient's subjective perception of the impact of disease and treatment on multiple dimensions of health status. Besides functional health, the effect of OSA on QOL is of interest in literature.2

According to the World Health Organization (WHO), health is defined as complete physical, mental and social well-being and not merely the absence of disease or infirmity. Thus, the health domain ranges from negatively valued aspects of life to the more positively valued aspects. The boundaries of definition usually depend on why one is assessing health and

This article was accepted: 22 May 2024 Corresponding Author: Azliana Aziz Email: az_aziz@usm.my the concerns of patients, clinicians and researchers.2 Franco et al. developed the QOL for children with OSA-18 questionnaire, which was first reported in 2000.³

At this point, there are limited QOL instruments available and adapted to the Malaysian population. Therefore, using other languages requires accurate, validated translation and awareness that they are specific to social culture. The instrument's measurement properties can be affected by cultural differences even though the translation is accurate. Reliability and validity must be determined to confirm that there is no influence of cultural differences. Therefore, validation of a questionnaire is important.²

Almost all the well-established and recognised screening questionnaires for OSA patients, such as Berlin, STOP-BANG and Epworth sleepiness scale, cater to the adult population. Most of the items in this questionnaire are not suitable for paediatric assessment of OSA. Proper screening tools for paediatric OSA patients are needed, which can be found in the OSA-18 questionnaire.

The OSA-18 is a brief, easily administered questionnaire, ideal for use during patient encounters. It has become the reason that it is the most widely utilised QOL instrument in paediatric OSA literature. It may also be used to measure the subjective aspects of OSA-related QOL reliably. The OSA-18 consists of 18 items grouped in five domains of sleep disturbance (4 items), physical symptoms (4 items), emotional symptoms (3 items), daytime function (3 items) and caregiver concerns (4 items). Each item is scored on a seven-point Likert scale (1 = none of the time, 2 = hardly any of the time, 3 = a little of the time, 4 = some of the time, 5 = good amount of the time, 6 = most of the time and 7 = all of the time), as shown in Figure 1. The OSA-18 has been validated as an evaluative and discriminative instrument in paediatric OSA.²

According to Franco et al., excellent test-retest reliability of OSA-18 was obtained for the individual survey items (R>0.74). Construct validity was shown by a significant correlation of the mean survey score with the respiratory distress index (R=0.43) and adenoid size (R=0.43). 3

There has been neither a national nor a translated instrument for assessment of QOL of paediatric OSA from literature reviews in Malaysia. The OSA-18 has waited for cross-cultural translation into the Malay language and appropriate pre-testing of the translated questionnaire. There can be advantages to translating the OSA-18 into Malay and introducing the Malay OSA-18 to determine the QOL of Malay children who suffer from OSA in clinical uses and research outcomes.²

PSG tests are limited to costly equipment, trained personnel and space requirements for the sleep lab. PSG is only available in selected and often specialised tertiary centres. There is insufficient such equipment available in most centres in Malaysia. This makes the screening, detection and identification of paediatric OSA patients not readily available in clinical settings, especially in primary practice.

The rationale of this study is to provide a reliable and valid tool to detect paediatric OSA patients in Bahasa Malaysia so that it can be readily applied to the majority of the patients in our setting in Malaysia. This questionnaire will facilitate early detection and hence early treatment of paediatric OSA pathology before disease progression leads to complications of diseases. It can also be applied locally regardless of the availability of a PSG machine, which is cost and time effective. Before conducting this study, written consent was obtained from the original author, Dr. Ramon A. Franco, Jr., MD, to translate his questionnaire into Bahasa Malaysia.

MATERIALS AND METHODS

Study Design

This was a cross-sectional study conducted in the Otorhinolaryngology-Head and Neck Surgery (ORL-HNS) Clinic, Hospital Universiti Sains Malaysia (HUSM) Kubang Kerian for 12 months from May 2021 until May 2022.

Study Population

For this study, 84 caregivers of paediatric patients and patients with OSA signs and symptoms were recruited from the outpatient department of ORL-HNS HUSM. Both patient and their caregiver were considered as one sample. The required sample size for this study is 65.4 Fortunately, during the period of the study, 84 samples were managed to be collected.

The age range of patients ranges from six months to 12 years. The patients with underlying cardiovascular diseases, lung diseases, neuromuscular diseases or mental retardation were excluded from the study. Children with any disease that has an impact on QOL, such as psychiatric disease and craniofacial anomalies were excluded. The patients who had already undergone adenotonsillectomy surgery and the children who were on sedative drugs were also excluded. Their caregiver must understand the Malay language well. The Malay OSA-18 questionnaire was answered by caregivers based on their observation of the child's symptoms and quality of health.

Written consent in Malay language was obtained from each participant (caregiver). All patients involved in this study answered the Malay version of OSA-18 in the ORL clinic. It was a self-administered questionnaire and took about 5 to 10 minutes for participants to complete it.

Sampling Method

The sampling method was done using the purposive sampling method whereby those patients who fulfilled the inclusion and exclusion criteria were included in the study.

Administration of the Questionnaire

The method of administration of the Malay version of the OSA-18 questionnaire was a self-administered technique.

Cross-cultural Adaptation

The translation aimed to ensure all contents of the questionnaire are equally clear, precise and equivalent in all ways to its original version. Therefore, the process of translation plays an essential aspect of a good questionnaire.

Table I: Mean age of samples and socio-demographic characteristic.

Descriptives			Statistic	Std. error
Age	Mean		8.8095	0.32775
	95% confidence interval for mean	Lower bound	8.1576	
		Upper bound	9.4614	
	5% Trimmed mean		9.0185	
	Median		9.0000	
	Variance		9.024	
	Std. deviation		3.00392	
	Minimum		1.00	
	Maximum		12.00	
	Range		11.00	
	Interquartile range		4.75	
	Skewness		-0.706	0.263
	Kurtosis		-0.329	0.520
			Frequency	(%)
Gender	female		31	36.9
	male		53	63.1
BMI	healthy		36	42.9
	underweight		2	2.4
	overweight		29	34.5
	obese		17	20.2
Palatine tonsil	grade1		3	3.6
	grade2		16	19.0
	grade3		44	52.4
	grade4		21	25.0
Adenoid	0-25 (grade 1)		13	15.5
	26-50 (grade 2)		20	23.8
	51-75 (grade 3)		30	35.7
	76-100 (grade 4)		21	25.0
OSA-18 results	Small		33	39.3
	Moderate		35	41.7
	Severe		16	19.0

Table II: The mean score for each domain.

Domain	Mean	SD
Sleep disturbance	14.70	4.36
Physical symptoms	15.43	4.54
Emotional symptoms	8.39	3.92
Daytime function	10.69	4.51
Caregiver concerns	14.48	5.66
Total score	63.62	17.79

Table III: Correlation validity between items in domains.

Item	Pearson correlation, r	p-value	
Item 1	0.425**	<0.001	
Item 2	0.801**	<0.001	
Item 3	0.806**	<0.001	
Item 4	0.637**	<0.001	
Item 5	0.715**	<0.001	
Item 6	0.745**	<0.001	
Item 7	0.795**	<0.001	
Item 8	0.547**	<0.001	
Item 9	0.854**	<0.001	
Item 10	0.843**	<0.001	
Item 11	0.707**	<0.001	
Item 12	0.786**	<0.001	
Item 13	0.867**	<0.001	
Item 14	0.825**	<0.001	
Item 15	0.803**	<0.001	
Item 16	0.907**	<0.001	
Item 17	0.846**	<0.001	
Item 18	0.888**	<0.001	

Table I	/-	Correlation	validity	hetween	domains
Table IV	v :	Correlation	validity	between	domains.

Variables/Pearson correlation r/p-value	Sleep disturbance	Physical	Emotional	Function	Worry	Total
Sleep disturbance	1	0.582**	0.339**	0.637**	0.610**	0.829**
Physical symptoms	0.582**	<0.001	0.002 0.328**	<0.001 0.491**	<0.001 0.476**	<0.001 0.753**
Triysical symptoms	<0.001		0.002	<0.001	<0.001	<0.001
Emotional symptoms	0.339**	0.328**	1	0.538**	0.272*	0.611**
	0.002	0.002		<0.001	0.012	< 0.001
Daytime function	0.637**	0.491**	0.538**	1	0.547**	0.831**
	<0.001	<0.001	<0.001		<0.001	<0.001
Caregiver concerns	0.610**	0.476**	0.272*	0.547**	1	0.792**
	<0.001	< 0.001	0.012	<0.001		< 0.001
Total score	0.829**	0.753**	0.611**	0.831**	0.792**	1
	<0.001	<0.001	<0.001	<0.001	<0.001	

Table V: Cronbach alpha for reliability test and test-retest reliability using the intraclass correlation (ICC) for each domain.

Cronbach alpha	ICC	95	CI	
		(Lower,	Upper)	p-value
0.608	0.989	0.982	0.993	<0.001
0.651	0.982	0.971	0.989	<0.001
0.726	0.982	0.973	0.989	<0.001
0.766	0.992	0.987	0.995	<0.001
0.885	0.991	0.986	0.994	<0.001
0.891	0.994	0.987	0.997	<0.001
	0.608 0.651 0.726 0.766 0.885	0.608 0.989 0.651 0.982 0.726 0.982 0.766 0.992 0.885 0.991	0.608 0.989 0.982 0.651 0.982 0.971 0.726 0.982 0.973 0.766 0.992 0.987 0.885 0.991 0.986	(Lower, Upper) 0.608 0.989 0.982 0.993 0.651 0.982 0.971 0.989 0.726 0.982 0.973 0.989 0.766 0.992 0.987 0.995 0.885 0.991 0.986 0.994

Step one of the translations began with the original English version of the OSA-18 questionnaire translated into the Malay language. The translation was done independently by two native Malay speakers, a medical officer from the otorhinolaryngology department and a professional translator without a medical background, who were both bilingual in Malay and English language. For this study, a professional high school English tutor who has a major in teaching English as a second language (TESL) was appointed. In step two, the translations were reviewed. A panel consisting of these two translators and the principal investigator critically reviewed the translation in forming the first draft of the Malay version of OSA-18. Subsequently in step three, another two independent professional translators who had no idea of the original version of the questionnaire translated this first draft into English. The back-translation was assessed for equivalence with the original English version.

Then step four involved six otorhinolaryngologists to review the first draft for content validity.5,6 After the establishment of the content validity, the expert committee comprising of these six otorhinolaryngologists, the translator and language professionals reviewed and discussed the discrepancies between the original, forward-translated and back-translated versions. Thus, in step five, the final version of the Malay version of the OSA-18 questionnaire was produced. The feedback forms of the translated OSA-18 questionnaire from these six otorhinolaryngologists were reviewed to establish content validity. In step six, the Malay version of the OSA-18 questionnaire was distributed to ten raters independently for face validity before applying it to the study population. This is to determine the clarity and comprehension of the

translated version. All of the raters gave 3 to 4 scores for the face validity questionnaire, which proves excellent translation. This indicates ease of understanding the contents of the translated questionnaire and the accuracy of the translation, thus no modification was done to the finalised version. Through these multiple steps, the Malay translation of OSA-18 was polished and finalised.

Validation of the Malay OSA-18

For this study, the patients were required to answer the questionnaire two times. For the first time, the patients were required to complete the Malay OSA-18 questionnaire on the same day during a clinic visit. Subsequently, they were given two weeks' follow-up appointments to answer the questionnaire for the second time. For the retest, intervals of two weeks were used for temporal stability.8 This means that it is short enough to prevent fluctuation in QOL status but long enough to prevent recall bias. During enrolment, all the selected patients will undergo nasoendoscopy and other clinical examinations to determine the adenoid and palatine tonsil size and grade. All of the patient's height and weight were also recorded to determine body mass index (BMI). The endoscopic findings will be scored based on the Brodsky modern assessment of tonsil and adenoid score.7 The relation between the symptoms in the OSA-18 questionnaire, endoscopic findings and BMI were analysed.

The questionnaire's internal validity and reliability were tested using Pearson's correlation, Cronbach α and interreliability coefficient tests. The descriptive analysis was used to summarise the socio-demographic features of all samples. The construct validity using Pearson's correlation test was determined by correlating the responses obtained for each

item with the other items in the OSA-18 questionnaire and between each domain in the OSA-18 questionnaire. The psychometric properties (reliability, consistency and reproducibility) were carried out by the internal consistency, test-retest reliability and inter-reliability coefficient tests. The reliability or internal consistency of items in the questionnaire was tested with Cronbach's $\alpha.$ A second OSA-18 questionnaire was administered to the patients two weeks following the initial test to test for test-retest reliability.8 The patients who suffered from common cold, influenza, tonsillitis or respiratory tract infection between two tests were excluded from the study.

The flow of methodology can be referred in Appendix.

Statistical Analysis

Statistical analysis was performed using SPSS version 26 (SPSS Inc, Chicago, IL). The descriptive analysis was used to summarise the socio-demographic features among the samples. The data obtained were expressed as mean (standard deviation, SD) for numerical and frequency (n, %) for categorical variables.

We applied Pearson's correlation, Cronhbach α and interreliability coefficient tests accordingly in the analysis. The p value of less than 0.05 was considered statistically significant. The construct validity by Pearson's correlation test calculated the inter-item correlation coefficient comparison between the five main domains (symptom scales) in the Malay OSA-18 questionnaire items.

The reliability or internal consistency of the items in the questionnaire was tested with Cronbach's α . Scores of 0.6-0.7 are acceptable, while a score of \geq 0.7 generally indicates good internal consistency.¹⁰

In test-retest reliability, two-way random average measures intraclass correlation coefficients (ICC), with a positive rating for reliability given at >0.70. ICC is a method to test the agreement between total scores on two different occasions by administering the Malay OSA-18 questionnaire twice and measuring its stability.¹¹

RESULTS

Demographic

This study involved 84 patients/samples, ranging from 6 months up to 12 years of age. The mean age was 8.80, with a standard deviation of 3.00 (Table I). The male gender contributes to 63.1% (n=53) of the sample, with the rest being female with 36.9% (n=31). About 42.9% of the patients were healthy, followed by overweight (34.5%), obese (17%) and underweight (2.4%). Among the samples, 96.4% presented with palatine tonsil enlargement, while 84.5% presented with adenoid enlargement. Samples presented with grade 3 palatine tonsillar enlargement were the majority with 52.4%, followed by grade 4 (25.0%), grade 2 (19.0%) and grade 1 (3.6%). For adenoid enlargement, the majority comes from grade 3 (35.7%), followed by grade 4 (25%), grade 2 (23.8%) and lastly, grade 1 (15.5%). Around 39% of the samples have a small impact on QOL, 42% have a moderate impact on QOL and 19% have a severe impact on QOL (Table I).

The OSA-18 questionnaire's lowest possible score is 18, while the highest possible score is 126. The mean total score of the OSA-18 questionnaire is 63.62 ± 17.79 , which indicates the data is normally distributed. Physical symptoms have the highest mean score at 15.43 ± 4.54 , while the lowest will be emotional symptoms (8.39 ± 3.92) (Table II).

Construct Validity

Pearson's correlation test demonstrated a significant positive correlation between the scores of each item in the OSA-18 questionnaire. All measured items are valid (p<0.001). The correlations were between 0.425 and 0.907, which shows a moderate to strong correlation. This shows that all the items in the questionnaire correlate to each other and measure the same thing while not being distinct from each other (Table III).

Pearson's correlation test also demonstrated correlation validity between domains. All domains are valid (p<0.05). The correlations were between 0.272 to 0.637, which showed weak to strong correlations. Pearson's correlation coefficients were rated as very weak (r<0.2), weak (r=0.20-0.35, moderate (r=0.35-0.30) and strong (r>0.5). 2

A two-tailed p-value <0.05 was considered statistically significant. Our study showed that item-to-item correlation was moderate to strong (0.425-0.907, p<0.01). However, if we pit each domain to one another, the correlation will be weak to strong (0.272-0.637, p<0.01).

The weakest correlation was between domain emotional symptoms and caregiver concerns (0.272). The strongest correlation was between sleep disturbance and daytime function (0.637). However, when compared to the total score, every domain has a strong correlation (0.611-0.831) (Table IV).

Reliability

Cronbach's α value between 0.6 and 0.8 is acceptable. In this study, the total Cronbach α was 0.891, and all domains were reliable, with Cronbach α ranging between 0.608 and 0.885. Deleting any items from the scales will affect the internal consistency (Table V).

Test-retest

- ICC estimates for sleep disturbance were 0.989, and their 95% confidence intervals were 0.982-0.993 based on a mean-rating (k=2), absolute-agreement, 2-way mixedeffects model.
- 2. ICC estimates for physical symptoms were 0.982, and their 95% confidence intervals were 0.971-0.989 based on a mean-rating (k=2), absolute agreement, and 2-way mixed-effects model.
- 3. ICC estimates for emotional symptoms were 0.982, and their 95% confidence intervals were 0.971-0.989 based on a mean-rating (k=2), absolute-agreement, 2-way mixed-effects model.
- 4. ICC estimates for the daytime function were 0.992, and their 95% confidence intervals were 0.987-0.995 based on a mean rating (k=2), absolute agreement, and a 2-way mixed-effects model.

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5. ICC estimates for caregiver concerns were 0.991, and their 95% confidence intervals were 0.986-0.994 based on a mean-rating (k=2), absolute-agreement, 2-way mixed-effects model.

The test-retest results for each item between the first and second measurements using ICC were excellent, and all domains are valid. The correlation is between 0.982 and 0.992, with a total score of 0.994 (Table V).

DISCUSSION

Quality of life is now recognised as an essential health outcome measure in clinical medicine. Measuring QOL involves using self- or caregiver-administered instruments to quantify the impact on emotional state, physical symptoms, and family interaction.¹³ Therefore, Malay OSA-18 can be very helpful as a screening tool to detect paediatric OSA patients in Malaysia.

The construct validity of the original study results was modest, particularly for the domains of emotional symptoms and daytime function. Given the multitude of factors that affect the QOL, the original author did not expect more than modest correlations to occur.³

The Pearson' correlation results can be affected by different demographic backgrounds too. All samples from our study came from Malay races, as Malay was predominant in Kelantan state, Malaysia. Lack of variation and sampling that did not include other races might not paint an overall picture of Malaysia's socio-demographic background, thus affecting the result. However, compared to the total score, every domain has a strong correlation (0.611-0.831, p<0.05). Overall, this Malay version of the OSA-18 questionnaire shows that all the items in the questionnaire significantly correlate with each other and measure the same thing while not distinct from each other. The Malay OSA-18 questionnaire can predict the severity of the impacts of OSA symptoms on the patient's QOL.

The OSA-18 questionnaire, because of its ease of administration, reliability and validity, is a practical means for the office-based determination of OSA-18 impacts on QOL. During our research, the participants were able to complete the questionnaire without difficulty in a short duration (5-10 minutes), and most of them did not need any assistance. The questionnaire was easy to understand, and the caregiver was comfortable answering all the items in the questionnaire. Furthermore, the questionnaire can be used in the outpatient setting with good acceptability and not as a burdensome tool. Analysis of the questionnaire's performance in the OSA-18 patients provides clinicians with a set of predictive parameters for various levels of OSA-18 impact on the patient's QOL.

The reliability of the Malay OSA-18 in assessing paediatric OSA patients was examined using the internal consistency Cronbach α . The overall internal consistency using Cronbach α (0.6-0.9) was acceptable and indicated its acceptable consistency. The stability of OSA-18 was demonstrated with test-retest by using ICC and showed excellent results

(correlation range from 0.982-0.992 with a total score of 0.994). This showed that OSA-18 has excellent test-retest results and indicates its stability.

A further second phase study needs to assess the quality of the Malay OSA-18 questionnaire quality. For example, further study needs to be done to determine response validity for patients who have undergone surgery. This is to see whether the Malay OSA-18 questionnaire can detect before-operation and after-operative changes and be used as an assessment tool to assess the quality-of-life improvement post-surgery. Other methods will be to see the external association of the Malay version of the OSA-18 questionnaire to another parameter (i.e., polysomnography, BMI, adenoid and/or tonsillar enlargement). A second phase study can be done and provide better tools, better understanding, and standardised treatment to paediatric OSA patients with the end of the pandemic.

CONCLUSION

The Malay obstructive sleep apnoea (OSA)-18 questionnaire is equivalent to the original English version. It is an effective tool to assess the paediatric OSA patients' symptoms and quality of life based on the validity, reliability and reproducibility values obtained. Therefore, its use is recommended in daily practice.

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