ORIGINAL ARTICLE

Validation of the Malay version of Berlin questionaire to identify Malaysian patients for obstructive sleep apnea

Yunus A, Seet W, Mohamad Adam B, Haniff J

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Authors:

Mohamad Adam Bujang, Bsc, MBA
(Corresponding author)
Biostatistics Unit,
Clinical Research Center,
1st Floor MMA House,124 Jalan Pahang,
53000 Kuala Lumpur,
Malaysia
Tel: +60340443060
Fax: +60340443080
Email: adam@crc.gov.my

Ashari Yunus, MD, MMED Int Med
Institute of Respiratory Medicine, Ministry of Health,
Kuala Lumpur,
Malaysia
Email: ashdr64@yahoo.com.au

Seet Wymen, MBBS, MPH
Clinical Epidemiology Unit,
Clinical Research Centre,
Kuala Lumpur,
Malaysia
Email: wymenseet@gmail.com

Jamaiyah Haniff, MD, MPH, MSc Clinical Epidemiology
Clinical Epidemiology Unit,
Clinical Research Centre,
Kuala Lumpur,
Malaysia
Email: jamaiyah@crc.gov.my

Abstract:

Objective: To validate the Malay version of Berlin Questionnaire (BQ) as a tool to screen for patients at risk of obstructive sleep apnea (OSA) in primary care
Background: Most patients with OSA are unrecognised and untreated. Thus, the BQ has been used as a tool to screen for patients at risk for OSA. However, this tool has not been validated in Malay version.
Materials and Methods: A parallel back-to-back translation method was applied to produce the Malay version (Berlin-M). The Malay version was administered to 150 patients in a tertiary respiratory medical centre. Concurrent validity of the Berlin-M was determined using the Apnea Hypopnea Index (AHI) as the gold standard measure. The test-retest reliability and internal consistency of the Berlin-M were determined.
Results: Most patients were males (64.0%) and majority of them were Malays (63.3%). Based on the sleep study test, 121 (84.0%) were classified as high risk while 23 (16.0%) as low risk using the Apnea Hypopnea Index (AHI) ≥5 as the cutoff point. The test–retest reliability Kappa value showed a good range between 0.864 – 1.000. The Cronbach's alpha of BQ was 0.750 in category 1 and 0.888 in category 2. The sensitivity and specificity were 92% and 17% respectively.
Conclusion: The BQ showed high sensitivity (92%) but low specificity (17%). Therefore, though the Berlin-M is useful as a screening tool, it is not a confirmatory diagnostic tool.

Introduction

Obstructive sleep apnea (OSA) is still an under-diagnosed and under-treated medical problem.[1] Sleep disturbances are common in the United States of America (USA) and the American Academy of Sleep Medicine reported that 46% of the population suffered from mild sleep apnoea, 34% had frequent snoring, 30% had insomnia and 25% struggled with excessive daytime sleepiness (EDS)[2] A cross sectional study of adults aged between 30-70 in Malaysia found that sleep disorders were pervasive. The prevalence of habitual snoring, sleep-disordered breathing and excessive daytime sleepiness were 47.3%, 15.2% and 14.8%, respectively. Seven percent of the respondents were suspected clinically of having OSA.[3]

Other co-morbidities associated with OSA which can lead to increased mortality include hypertension, increased risk of cardiovascular disease and pulmonary hypertension. Hence, it is essential that OSA is diagnosed early and

treated to improve patients' quality of life. A Canadian study found that people with OSA are at double the risk of being in a car crash.[4] However, approximately 80% of people suffering from moderate to severe OSA have not been clinically diagnosed.[5]

The gold standard for diagnosing OSA is the attended overnight level I polysomnogram (PSG). It requires the patient to be admitted overnight at a medical facility which has a sleep study centre. Polysomnography is used to measure the apnoea-hypopnoea index (AHI) and other parameters; the severity of OSA is measured with the AHI, which is the number of apnea and hypopnea events per hour of sleep.[6] The American Academy of Sleep classifies OSA as follows: presence of OSA (AHI ≥ 5), mild OSA (AHI of 5 to 15), moderate OSA (AHI of 16 to 30) and severe OSA (AHI > 30).[6] The sleep study services are limited and costly. Hence, there is a need for an instrument to screen for possible OSA.

A number of screening tools are available such as the BQ and Epworth Sleepiness Scale (ESS). The latter, a scale intended to measure average daytime sleepiness, is basically a self-rating form consisting of eight questions. The questions are designed to assess daytime sleepiness and scores range from 0-24, with scores higher than 16 indicating severe daytime sleepiness .[7] The BQ contains 10 questions covering three categories that identify risks of OSA and it was chosen as the study instrument.

The BQ is a validated instrument used to identify individuals at risk of OSA. It was developed based on the findings of the Conference on Sleep in Primary Care held in April 1996 in Berlin, Germany. It has been evaluated in the population of Cleveland, Ohio with a sensitivity of 86% and specificity of 77%. Literature was reviewed and factors or behaviours that persistently correlated to the presence of sleep-disordered breathing across all studies were included in the questionnaire. The final questionnaire only focused on a limited set of known risk factors for OSA .[8] Previous studies have successfully used the BQ to predict sleep-disordered breathing. The BQ contains 10 questions on three categories: severity of snoring, excessive daytime sleepiness and history of high blood pressure or obesity. The patient is instructed to answer all the questions, and the physician or medical staff analyses the responses. If the individual scores positive in at least two of the three categories, the patient is at high risk for OSA. However, if the patient scores positive in only one or none of the categories, then the patient is deemed to be at a low risk for OSA.[8]

Currently, there is no tool available in the Malay language to screen for OSA. Therefore, the objective of this study was to validate the Malay version of the BQ (Berlin-M) to identify population at risk for OSA in Malaysia.

Materials and Methods

The study process

This study was conducted in three phases. In phase 1, the BQ was translated from English to Malay. Phase 2 was the pre-testing of the pre-final version of the translated questionnaire and in phase 3, a validation study was carried out. This study spanned from June 2006 to December 2008.

Phase 1 (Translation process)

The translation process adhered to the guideline of cross-cultural adaptation by Beaton et al to ensure that the contents and meanings were preserved. [9] The aim was to evaluate the clarity, comprehensibility, and adequacy of wording to ensure that they can be understood by the Malaysian population.

Two forward translations were produced; one by a clinician involved in OSA clinic (and therefore not blinded to the study), and the other by a certified translator from the Malaysian National Institute of Translation (who was blinded to the study). They produced the M1 and M2 versions which were later

back translated to English (the E1 and E2, respectively) independently by a certified translator and a clinician. The researchers and the translators then formed the expert panel which reviewed all the different versions - the original, two forward and two backward translations.

The pre-final Malay version of the BQ was produced by comparing E1 and E2 with the original English version. This was done by choosing the Malay version, which produced the back-translation that was closest to the original English version. Thus, the best translations were merged to produce the final harmonised version.

Phase 2 (Pre-test)

Seven subjects took the pre test for the Berlin-M in the Institute of Respiratory Medicine (IRM). The subjects had passed a fluency and translation test and are considered bilingual.
Each subject was given five forms - the Patient Information sheet, assent and consent forms, demographic form and two versions of the Berlin OSA Questionnaire. The Malay and English versions were administered at random sequence followed by a focus group discussion on each item in the questionnaires. They were asked whether the words and terms used in the Malay version were clear, relevant and comprehensible. The subjects agreed that Berlin-M was straightforward and easy to understand.

Phase 3 (Validation)

The Berlin-M was later tested for its reliability and validity among 150 subjects in the same institute. 150 study subjects were enrolled. They were selected from the patients referred to IRM for overnight PSG using a convenience sampling. The subjects were asked to fill in the patient information sheet as well as a self-administered questionnaire which took them about 20-30 minutes to complete. The subjects answered the Berlin-M before the overnight PSG and during the follow up visit to the IRM.

Study design

This cross sectional study was conducted in a single centre and the study participants were patients diagnosed with OSA. Samples were selected consecutively from new cases referred to the institute according to the inclusion and exclusion criteria listed below.

Inclusion criteria:

All patients who satisfy these criteria

- ≥18 years old
- Malay language literate
- Suspected OSA, if at least one of the following symptoms appears:
  - > Excessive daytime sleepiness
  - > Loud snoring
  - > Unrefreshing sleep

Exclusion criteria:

- Patients with major systemic co-morbidity such as chronic obstructive pulmonary disease or cardiac failure
- Patients with respiratory infections

Ethical Approval

This study has received ethical approval from the Ministry of Health Malaysia (MRG-2004-17)

Statistical methods

The test-retest reliability was conducted among the same study population two weeks after the initial test and it was assessed using the Cohen's Kappa statistic. Weighted Kappa was used for questions with multiple-point answers. Internal consistency was assessed using the Cronbach's alpha coefficient. The sensitivity and specificity were calculated using AHI ≥ 5 as the cutoff point for high AHI and AHI < 5 as low or normal.

Study instrument

The patients completed a self-administered demographic data collection form which included age, sex, ethnicity, education and the Berlin-M questionnaire. Polysomnography (PSG) machine was used as basis of gold standard and to validate Berlin-M questionnaire.

Results

Profile

A total of 150 subjects were recruited but only 144 were included in the final analysis as six patients did not complete the overnight PSG. Most subjects were male (64.0%) and Malay (63.3%) with a mean (SD) age of 44.7 (11.5) years. The mean (SD) of neck circumference (cm), body mass index (kg/m2), hip circumference (cm), waist circumference (cm) and systolic blood pressure (cm) were 39.3 (4.9), 36.3 (11.2), 110.0 (19.2), 94,1 (16.9) and 129.4 (14.6), respectively. Majority of the patients were obese and had high blood pressure (Table 1).

Reliability

A high test-retest reliability was recorded in the range of 0.892 – 1.000 (Table 2). The Cronbach's alpha coefficients were calculated for each category; category 1 and 2 showed Cronbach's alpha of 0.750 and 0.207, respectively. Cronbach's alpha for category 2 was low because item 9 enquired how often patients nodded off or fallen asleep while driving but many of the participants did not drive. When item 9 was deleted, the Cronbach alpha coefficient for category 2 rose to 0.888 (Table 3).

Validity

The Berlin-M had a sensitivity of 92% and specificity of 17%. In view of the high sensitivity, the Berlin-M questionnaire can be considered as a screening tool for OSA (Table 4).

Table 1: Patient's characteristics and clinical profile

Variable (s)	n (%)	Mean (SD)	Min, max
Age (n=150)		44.7 (11.5)	23.0, 76.0
Sex (n=150)			
• Male	96 (64.0)	-	-
• Female	54 (36.0)	-	-
Ethnicity (n=XX)			
• Malay	95 (63.3)	-	-
• Chinese	30 (20.0)	-	-
• Indian	24 (16.0)	-	-
Neck circumference (n=148)	-	39.3 (4.9)	22.0, 52.0
Body mass index (kg/m2)	36.3 (11.2)	19.7, 81.7	(n=149)
Hip circumference(cm)	110.0 (19.2)	75.0, 185.0	(n=147)
Waist circumference (cm)	94.1 (16.9)	65.0, 150.0	(n=148)
Blood pressure (mmHg)	(n=144)		
• Systolic		129.4 (14.6)	98.0, 191.0
• Diastolic		82.2 (9.9)	55.0, 109.0
AHI reading (n=144)		38.8 (31.9)	0.0, 113.0
AHI two categories (n=144)			
• Low/Normal (<5)	23 (16.0)		
• High (>5)	121 (84.0)		

Table 2: Test – retest reliability of Berlin-M Questionnaire

Item no.	Kappa
1	1.000
2	1.000
3	0.949
4	0.919
5	0.877
6	0.864
7	0.890
8	1.000
9	0.892
10	0.930

Table 3: Reliability of Berlin-MQuestionnaire

Category	Item (Likert scale only)	Cronbach's alpha
1	No. 2, 3 and 5	0.750
2	No. 6, 7 and 9	0.207
	No. 6 and 7	0.888*

**Note: Item 9 was excluded because more than half of the patients did not drive.*

Table 4: Sensitivity, specificity, positive and negative predictive values of Berlin-M Questionnaire using AHI categories

Sensitivity	0.92
Specificity	0.17
Positive predictive value	0.97
Negative predictive value	0.29

Discussion

Our findings show that Berlin-M is a reliable and valid screening tool for OSA. However, its low specificity renders it unsuitable as a confirmatory tool to diagnose OSA. Overnight PSG is the recommended "gold standard" for the diagnosis of OSA. However, it requires patients to stay overnight in a hospital which has a sleep study facility. As a result of overwhelming demand and limited resources, there is significant delay in the diagnosis and treatment of patients with OSA. This increases the mortality and morbidity as a study has shown that incidences of non-fatal and fatal cardiovascular events escalate in untreated severe OSA.[10] A screening tool is useful in stratifying patients who have a high suspicion of OSA so that they can undergo proper diagnostic test and treatment. our study found promising results from Berlin-M as a validated instrument in Malay language to screen patients for OSA in Malaysia

The Berlin-M showed good sensitivity (92%) with low specificity (17%) when the cut off was AHI ≥ 5. A study in Portugal reported a sensitivity of 72% but a higher specificity (80%).[11] A study using the Arabic version of the BQ showed a sensitivity of 97% and specificity of 90% which validates the fact that a translated BQ can be a reliable screening tool.[12] A study conducted in India using a Hindi version of the BQ also showed high sensitivity (86%) and specificity (95%).[13] The Berlin-M, however, had a high sensitivity but low specificity.

The results also showed that a majority of the patients were obese and had high blood pressure. They were consistent with a study conducted in Brazil and USA which reported that hypertensive and obese subjects had a higher chance of being diagnosed with OSA.[14] A Turkish study found that body fat composition and BMI are significant predictors for OSA.[15]

The Berlin-M showed high test-retest reliability for all categories with values higher than 0.8, which affirmed the quality of the translation. This study found that a good translation of BQ can achieve a high test-retest reliability as attested by an earlier

study in Malaysia.[16] Thus, the Berlin-M was well translated cross-culturally and the participants understood the content and were able to answer all the questions.

Limitations

The study involved the sleep-study clinic population from only one centre. The findings, therefore, do not represent the general population. However, if the study were to be conducted in outpatient clinics, for example those with access to the general population, it can provide a better overall picture of the utility and validity of the Berlin-M. This study also excluded patients who were diagnosed with depression and hypothyroidism, who can present with symptoms similar to OSA. This may complicate the treatment and diagnosis of OSA.[17, 18]

Conclusion

The Berlin-M has a high sensitivity (92%) but low specificity (17%). This suggests that it may be used to screen for OSA symptoms but is poor in confirming whether a person has clinical OSA. It also has a good positive predictive value though the negative predictive value is poor. i.e. if it is tested positive, it is more likely that OSA is present; whereas if it is tested negative, it cannot rule out the absence of OSA. Therefore, Berlin-M cannot be used to confirm the diagnosis of OSA but can still serve as a useful screening tool for patients who may have OSA. For example, Berlin-M can be used to screen patients in primary care needing referral to the tertiary centre to confirm the diagnosis and for further management. Moreover, the Ministry of Health is planning to partner with the Transport Ministry to screen bus drivers for sleep disorders in order to diagnose and treat OSA. The Berlin-M can be considered as a screening tool for OSA among the drivers.[19]

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