Original Article

Development and Validation of a Thai Version of the Sleep Apnea Quality of Life Index (SAQLI)

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Objective: To develop a Thai version of the Sleep Apnea Quality of Life Index (SAQLI-T) and evaluate its reliability and validity.

Materials and Methods: A cohort of 506 Thai sleep apnea patients were recruited. All participants were required to complete the short form questionnaire on various aspects, or domains, of their condition, including daily functioning, social interaction, emotional functioning, and symptoms. The internal reliability of the questionnaire had been tested. In order to examine the external reliability (test-retest reliability), 30 subjects were recruited to answer the SAQLI-T twice at two weeks apart. The construct validity was compared with apnea-hypopnea index (AHI).

Results: The Cronbach's alpha of internal reliability was 0.90 and excess 0.7 in all domains, and the intra-class correlation coefficients of external reliability were 0.93. The correlation between the construct validity and AHI was weak. However, the predictive validity of the test showed a significant lower mean of total SAQLI scores observed in participants with mild to moderate obstructive sleep apnea (OSA) compared to those with severe OSA.

Conclusion: The SAQLI-T as developed demonstrated a high level of internal consistency and a high test-retest reliability, although there was a weak correlation with AHI. A short form SAQLI is easy to use in daily practice as well as in the research settings, and therefore, it is a useful health-related quality of life measure.

Keywords: Questionnaire, Sleep apnea, Sleep-disordered breathing, Quality of life

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Obstructive sleep apnea (OSA) is a widespread sleep disorder worldwide, including Thailand. The prevalence of OSA (apnea-hypopnea index [AHI] 5/hour) in Thailand was 11.4% in 2011[1]. The risk of hypertension, cerebrovascular disease, and ischemic heart disease significantly increase in severe cases of sleep apnea, and the risk of an automobile accident and accident while operating industrial equipment are also heightened[2,3]. A multi-disciplinary approach to the treatment of sleep apnea is necessary to mitigate these risks. An attended single-night comprehensive polysomnography is the gold standard for assessment of the severity of sleep-disordered breathing[3]. The most effective treatment and widely used for OSA is continuous positive airway pressure (CPAP) therapy. Treatment for sleep apnea also consists of weight reduction, appropriate body positioning during sleep, dental appliances, and medical[4] and surgical treatment[5].

The predominant symptom of OSA is daytime somnolence from poor sleep quality, which obscures many other problems, such as a morning headache, unrefreshed feeling on awakening, fatigue, tired, depression, and decreased cognitive function. Excessive sleepiness from sleep apnea may negatively affect the ability to learn, work, and have interpersonal relations, which directly degrade the health-related quality of life (QOL). Many studies have shown reductions in the patient's general health status resulting from sleep-disordered breathing, where treatments with nasal continuous positive air pressure have been associated with increases in quality-adjusted life years[6]. However, other studies have shown a poor

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relationship between disease severity assessment and general QOL[7]. Nonetheless, the patient's well-being and QOL should be measured and integrated into a comprehensive evaluation of sleep apnea.

Although sleep apnea treatment in Thailand can achieve the international standard, there are few studies of the patient's perception of their QOL. Assessment of the patient's perspective is also important for the evaluation of the results after treatment. The Medical Outcomes Survey Short Form-36 (SF-36) for QOL is not disease-specific for sleep-disordered breathing. Some domains examined by this non-specific questionnaire might not seem relevant to patients with sleep apnea. The specific symptoms and concerns associated with sleep apnea, not addressed by this type of questionnaire, should be addressed when assessing the effects of the sleep apnea on quality of life.

The Calgary Sleep Apnea Quality of Life Index (SAQLI), developed by Flemons et al, may be one of the most commonly used questionnaires to assess the health-related QOL of the patients with sleep apnea and snorers[8,9], which is also available in short form. The short Calgary SAQLI was developed based on the rank order of the frequency importance product. The short Calgary SAQLI has 14 questions organized into four domains, which are daily functioning, social interactions, emotional functioning, and symptoms. A fifth domain, treatment-related symptoms, was the additional parameter to evaluate the active intervention trials possible effect on QOL. Statistically, the SAQLI has a high level of internal reliability as shown by high intraclass correlation coefficients (ICC) and high construct validity as proved by its positive correlations with the SF-36 and responsiveness was also high with improvement mean change in scores in patients successfully completing CPAP therapy over four weeks. Clinically, this questionnaire is well designed and developed for selected important outcomes for especially patients who suffered from sleep apnea and snoring.

In Thailand, there is a need for an instrument to evaluate the health-related quality of life of sleep apnea patients. The current study aimed to develop a Thai version of the Sleep Apnea Quality of Life Index (SAQLI-T), and evaluate its validity and reliability. The widely used disease-specific SAQLI was used as a basis for the Thai version.

Materials and Methods

The present study was conducted between June 2010 and August 2016. All procedures performed in the studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Ethics approval was obtained from of the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. (IRB No 201/54). All participants provided written informed consents.

Translation of the original SAQLI into Thai

After obtaining the approval for the translation of the SAQLI into the Thai language from the original author (Flemons), the authors first translated it from English into Thai language. Two Thai native speakers who are fluent in English, a professional translator and a physician who is experienced in the management of sleep apnea, did the translation independently. Another translator performed backward translation from Thai into English language. Both versions of SAQLI were reviewed for the content and word format by expert opinion before the pilot testing. Then the authors conducted the SAQLI-T test in 30 sleep apnea patients. The principal investigator interviewed each. The interview was focused on any item that was difficult to answer, confusing, difficult to understand, upsetting/offensive, or redundant of items, as well as identifying missing items. The patients were asked to make any suggestions on each item, changing the alternative wording or paraphrasing. After reviewing and analyzing a few of in-depth interviews, the revised version was tested in the pre-testing group again. Three rounds of qualitative analysis were done before proceeding to the final draft of SAQLI-T.

Subjects

Thai sleep apnea patients who had been diagnosed by the standard overnight polysomnography at the sleep laboratory, King Chulalongkorn Memorial Hospital were included. Patients who are unable to read or understand the questionnaire were excluded from the study.

Data collection

Method of data collection: All eligible participants completed the first self-administration of the final version of the SAQLI-T while attending the sleep test at the sleep laboratory at King Chulalongkorn Memorial Hospital. A skilled sleep technologist scored the polysomnogram and reconfirmed by a sleep disorder specialist. Sleep technologist and physician did not know the questionnaire results. On a visit

two weeks later, 30 patients randomly chosen by a computer program answered the SAQLI once again in order to evaluate its repeatability.

Operational definitions: Sleep study diagnosis was done with the Compumedic polysomnography (Compumedics, Abbots-ford, Australia) with manual analysis of all tracings.

Sleep apnea severity is classified as follows, AHI 5 to 15 per hour as mild, 15 to 30 per hour as moderate, and equal to or greater than 30 as severe[10].

The SAQLI was developed by Flemon et al[9]. It is a set of self-administered questionnaires consisting of 14 questions regarding four QOL domains including daily activities, social interactions, emotions, and symptoms. Each question has seven response options, scored as 0=not at all/no difficulty, 1=a small amount, 2=a small to moderate amount, 3=a moderate amount, 4=a moderate to large amount, 5=a large amount, 6=a very large amount. The SAQLI score is calculated by adding the individual scores for each of the 14 questions and divided by 14. The missing score in one or two items of the SAQLI was replaced by the mean of the items to which the participant had responded.

Statistical analysis

Sample size calculation: The appropriate sample size for the present survey was calculated by using a confidence interval (CI), which was derived for Pearson correlation coefficient. With N for reliability 0.70 (24), if α level was 0.05 and CI value was 0.10, then a minimum of 180 participants were needed to achieve the reliability testing. Calculation for response rate is approximately 90%, so the number of patients required was around 200.

All statistical analyses were carried out with the SPSS software for Windows version 17.0 (Chicago, Illinois, USA). A descriptive analysis was done of the clinical parameters as well as the QOL parameters expressed as a mean ± standard deviation (SD) for the quantitative variables.

The internal consistency reliability of the scale items was assessed by calculating Cronbach's alpha coefficients, with minimum criterion value 0.70. The ICC was tested as an assessment of external consistency reliability at both the start and two weeks later. A good correlation was considered when ICC values were higher than 0.71 and moderate for value between 0.51 to 0.70.

Clinical validity was assessed by content validity and construct validity. Content validity evaluation was done, using the responses of 30 sleep apnea patients during their private interview, by the principal investigator and reviewed by independent experts including three bilingual health professionals, which were two independent physicians, and an experienced nurse. The draft questionnaire was reviewed for its question design, vocabulary, and any other aspects of the questions and response categories, and instructions to participants.

Construct validity was calculated by dividing the number of incomplete responses, by the complete responses, multiplied by 100. A percentage result of 30% or more was acceptable. Construct validity was calculated with Pearson's or Spearman's correlation coefficients, which were used depending on the normality of distribution of the variables. The predictive validity was analyzed by comparing the groups of patients with severe and non-severe OSA according to an AHI cut-point of 30 using the Student's t-test for independent means. A p value lower than 0.05 was considered significant.

Table 1. Demographic characteristics

General characteristic	n (%)
Number of patients	506 (100)
Sex	
Male	299 (59.09)
Female	207 (40.91)
Age (years), Mean±SD	50.51±14.11
Sleep apnea severity	
Mild (5≤AHI<15)	57 (11.3)
Moderate (15≤AHI<30)	94 (18.6)
Severe (AHI≥30)	355 (70.2)
AHI (event per hour), Mean±SD	36.46±32.70

AHII=apnea-hypopnea index; SD=standard deviation

Results

Subject characteristics

Five hundred six patients were included in the present study. The patients' demographic characteristics are presented in Table 1. Sixty percent of the patients were male. The mean±SD age was 50±14 years (range 18 to 84). Seventy percent of the patients were diagnosed with severe OSA and the mean AHI was severe (mean±SD AHI was 36±32 /hour).

Reliability

Internal consistency: Cronbach's alpha coefficient for the SAQLI-T was 0.90 for all 14 items with a range from 0.70 to 0.89 for all domains. The Cronbach's alpha coefficient were obtained for each of the four domains, daily activities with 0.77 (95%

Table 2. Internal consistency assessed by calculation of Cronbach's alpha

Domain	Questions	Mean±SD	Cronbach's alpha (95% CI)
A: Daily activities	1, 2, 3, 4	10.09±4.84	0.77 (0.74 to 0.79)
B: Social interactions	5, 6, 7, 8	10.02±4.56	0.70 (0.66 to 0.73)
C: Emotions	9, 10, 11	6.52±3.58	0.76 (0.73 to 0.79)
D: Symptoms	12, 13, 14	8.25±4.42	0.89 (0.87 to 0.90)
Total score		35.82±14.60	0.90 (0.89 to 0.92)

SD=standard deviation; CI=confidence interval

Table 3. External consistency (test-retest) assessed by calculation of intraclass correlation coefficient

Domain	Test-retest ICC (95% CI)
A: Daily activities	0.86 (0.71 to 0.93)
B: Social interactions	0.87 (0.72 to 0.94)
C: Emotions	0.88 (0.75 to 0.94)
D: Symptoms	0.87 (0.73 to 0.93)
Total score	0.93 (0.84 to 0.96)

ICC=intraclass correlation coefficient, CI: confidence interval

Table 4. The construct validity assessed measuring correlation between the SAQLI-T and AHI by calculation of Pearson's correlation

Domain	Pearson's correlation
A: Daily activities	0.13
B: Social interactions	0.15
C: Emotions	0.10
D: Symptoms	0.12
Total score	0.14

AHI=apnea-hypopnea index; SAQLI-T= Thai version of sleep apnea quality of life index; OSA=obstructive sleep apnea

CI 0.74 to 0.79), social interactions with 0.70 (95% CI 0.66 to 0.73), emotional functioning with 0.76 (95% CI, 0.73 to 0.79), and symptoms with 0.89 (95% CI 0.87 to 0.90). The symptoms domain exhibited the highest internal consistency. The Cronbach's alpha obtained for each of the domains was higher than 0.7, which indicated a good to excellent internal consistency (Table 2).

External consistency: The score at both initial and two-weeks-apart was investigated by ICC of the four domains and the SAQLI-T. Test-retest reliability was measured in 30 patients and found to be excellent with a value of 0.93 in total scores with a range from 0.86 to 0.88 in each domain (Table 3). The following ICC were obtained for each of the four domains, daily activities with 0.86 (95% CI 0.71 to 0.93), social interactions with 0.87 (95% CI 0.72 to 0.94), emotional functioning with 0.88 (95% CI 0.75 to 0.94), and symptoms with 0.87 (95% CI 0.73 to 0.93). The lowest reproducibility was found in the domain of daily activities.

Construct validity: The construct validity of the SAQLI-T was tested by measuring the correlation between the SAQLI-T and AHI, as shown in Table 4. Correlations between SAQLI-T daily functioning domain, symptoms domain, and SAQLI-T exhibited weak correlations with AHI.

The social interaction functioning domain of the SAQLI-T exhibited the highest correlation with AHI (Pearson's r 0.15, $p<0.01$), and the emotional domain exhibiting the lowest correlation with AHI (Pearson's r 0.1, $p<0.01$).

Comparisons of subgroup severity of OSA were also performed to determine the construct validity of the SAQLI-T, as illustrated in Table 5. The number of participants with mild to moderate OSA was 144 patients, and 399 patients had severe OSA. The mean AHI of the mild to moderate OSA subgroup was 16.67±7.37 per hour, and the severe OSA subgroup was 63.44±29.90 per hour. A significantly lower mean of the total SAQLI scores was observed in participants with mild to moderate OSA as compared to those with severe OSA. Subscale analysis demonstrated the social interaction and emotional scores were also significantly lower in participants with mild to moderate OSA compared to severe OSA subgroup.

Discussion

The evaluation of patients' QOL has become important in health care services. OSA is a disorder that leads to impairment of health-related QOL. Many tools have been developed to achieve a reliable instrument which reflects the patient's QOL. The most popular one is the SF-36[11]. However, this questionnaire is a non-specific tool for assessment of health-related QOL in sleep apnea patients. The others include Euro-QOL[12], General Health Questionnaire(13), Nottingham Health Profile[14], and SAQLI[8].

Table 5. Mean SAQLI scores by OSA severity subgroups

Variable	SAQLI score, Mean±SD		p-value (95% CI)
	Mild/moderate OSA	Severe OSA	
A: Daily activities	10.40±4.62	11.18±5.17	0.09 (–1.71 to 0.136)
B: Social interactions	9.25±4.60	10.51±4.53	0.01* (–2.11 to –0.39)
C: Emotions	5.97±3.31	6.79±3.73	0.01* (–1.47 to –0.15)
D: Symptoms	7.84±4.48	8.43±4.42	0.16 (–1.42 to –0.24)
Total score	33.71±14.47	37.03±14.81	0.01* (–6.09 to –0.54)

CI=confidence interval; SAQLI=sleep apnea quality of life index; OSA=obstructive sleep apnea

The Calgary SAQLI is a questionnaire that can be used to evaluate the health-related QOL of these patients. The original SAQLI was reported to have excellent measurement properties with evidence of validity as a discriminative index and a high-reliability coefficient on testing and retesting at two-week intervals. This test also has a very high responsiveness index and an effect size, which was much greater than the SF-36 in terms of evaluating the effect of sleep apnea. The SAQLI also had a range of correlations at baseline with the SF-36, the Epworth Sleepiness Scale, and the global rating of the QOL[8,9]. This questionnaire has never been translated into Thai before.

The authors developed and evaluated the validity and reliability of a SAQLI-T in a tertiary center in Thailand. This questionnaire was administered to a cross-sectional sample of 506 Thai OSA patients that have been polysomnography tested in a standard lab. The large sample size was an advantage to the collected data because accuracy was established, and biases were reduced. More than half of the patients were diagnosed with severe OSA, and the mean AHI was severe, which is expected for a referral population in a tertiary center.

The present study demonstrated the high reliability of the SAQLI-T. That is, the overall internal consistency and external consistency of questionnaire had excellent correlation and reproducibility. The high correlation of internal consistency was similar to the previous studies of the original English version of SAQLI Cronbach's alpha (0.88 to 0.92)[9], as well as Spanish (0.78 to 0.82)[15], Japanese (0.82 to 0.93)[16], Chinese (0.82 to 0.93)[17], Korean (0.67 to 0.92)[18], Persian (0.79 to 0.84)[19], and Malay(0.95 to 0.99)[20] versions. The internal consistency of each item had a good correlation, which indicated that each item corresponds well with other items in its domain especially in symptom domain had an excellent correspondence. The intraclass correlation values (ICC) for assessing external consistency also indicated high reproducibility (ICC 0.86 to 0.93). These findings were similar to previous studies of the original English, as well as Chinese, Japanese, and Korean versions. All these versions had excellent intraclass correlation coefficients (ICC: English version 0.72 to 0.92, Chinese version 0.73 to 0.91, Japanese version 0.71 to 0.83, and Korean version 0.67 to 0.92).

To confirm the construct validity, the AHI was used to measure the QOL, which was an important physiologic measurement unique to sleep apnea patients and more relevant. Other health-related QOL questionnaires such as SF-36 were not used in the comparison in the present study because previous studies carried out in Asian population assessed the QOL using SF-36 in sleep apnea patients and found no relationship between QOL and the severity of sleep apnea[21].

The correlation between all functioning domains and AHI are weakly positive. A similar finding was found in the other health-related QOL questionnaire translated to Thai. The Thai version of the Functional Outcome Sleep Questionnaire[22] demonstrated a weak correlation between global scores and AHI. The results implied that AHI was not an excellent predictor for psychosocial and functional aspects of health. This weak positive correlation may be because sleep apnea patients may have other problems that can cause limitations in their psychosocial functioning such as their underlying disease, overweight, and difficulty concentrating. However, as for the predictive validity of the SAQLI test, it was demonstrated that a significantly higher mean of total SAQLI scores was observed in participants with severe OSA compared to those with mild to moderate OSA. This finding is also coherent with the Malay version of SAQLI, which demonstrated a statistically significant difference in the SAQLI scores among patients with mild to moderate and severe OSA. These findings support the usefulness of SAQLI in detecting differences in functional psychosocial outcomes across different levels of apnea severity. The Malay version also demonstrated a significant correlation between severity of OSA in

all subscale domains, which is a difference, as the Thai version revealed associations only in domains of social interaction and emotion. The other previous studies of the predictive value of SAQLI scores in discriminating between groups of patients categorized by AHI, found that the Persian[19], Korean[18], and the first English[9] versions were unable to discriminate between groups of patients categorized by AHI. The finding did not demonstrate any statistically significant difference in the SAQLI scores among patients with mild, moderate, and severe OSA.

Limitation

There are four limitations associated with the present study. First, it should be mentioned that every patient who came to the sleep laboratory was asked whether they wish to enroll in the present study, which may result in selection bias. Second, in the original manuscript, the severity of the subjects ranged from mild to severe. In Thailand, the authors conducted the study in the tertiary center, and most of the patients were diagnosed with severe OSA, which may affect the generalizability of the questionnaire but may be useful in clinical settings in advanced tertiary care. Third, the present study did not divide baseline characteristics by educational level, occupation and marital status, which may affect QOL. Finally, the authors did not explore the factor structures of SAQLI and sensitivity to change after CPAP treatment. To the authors' knowledge, four previous studies, the Chinese version[17], the Portuguese version[23], the Spanish version[15], and the Malay version[20], had performed a factor analysis of SAQLI. In all of the translated versions, the loading of items of the factors was not necessarily similar to the original domains. Furthermore, the sensitivity analysis that done in previous studies[16,17] demonstrated that all SAQLI domains showed significant changes of SAQLI after the beginning of CPAP treatment. It is suggested that more studies are required to explore the responsiveness of SAQLI to demonstrate sensitivity to change induced, not only by CPAP treatment but also by sleep surgery and the use of oral appliances in Thai populations.

Conclusion

The SAQLI-T has been developed, which demonstrated a high level of internal consistency and test-retest reliability. The construct validity was weakly correlated with AHI, but with a significantly lower mean of total SAQLI scores in participants with mild to moderate OSA as compared to those with severe OSA. A short form of SAQLI provides a useful measure of HRQOL which is simple to utilize in daily practice as well as in research settings.

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Declaration

The ethics, consent and permissions: Ethics approval was obtained from of the Institutional Review Board of the faculty of Medicine, Chulalongkorn University, Bangkok, Thailand (IRB No.201/54). All participants provided written informed consent for the study.

Competing interests: All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

Conflicts of interest

The authors declare no conflict of interest.

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