Psychometric properties of the Lithuanian version of Sleep Apnea Quality of Life Index (a pilot study)

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Key words: *obstructive sleep apnea; Calgary Sleep Apnea Quality of Life Index; snoring; radiofrequency ablation.*

Summary. *Objective. To arrange and test for its psychometric properties Lithuanian version of Sleep Apnea Quality of Life Index and assess quality of life among snoring and obstructive sleep apnea patients before and after the treatment.*

Material and methods. Cross-cultural adaptation of Lithuanian version of Calgary Sleep Apnea Quality of Life Index was accomplished according to generally accepted methodology. In total, 36 (29 males and 7 females) patients (mean age, 41.1±9.7 years) suffering from socially disturbing snoring and obstructive sleep apnea were included into the study. All patients underwent complete full-night polysomnography (mean apnea/hypopnea index, 12.7±11.2) and were treated with two sessions of radiofrequency tissue ablation at the palatal and tong base (if it was necessary) levels.

Lithuanian version of the Calgary Sleep Apnea Quality of Life Index was presented before the treatment with radiofrequency tissue ablation and in the period of 2 to 3 months after the treatment. Thirty-five patients repeated the same questionnaire after three weeks to assess the reliability of scores.

Results. The Cronbach's α coefficients of internal reliability were above the standard (0.7 for groups) in all subdomains and domains. Test-retest correlation coefficients for each domain (ranged from 0.92 to 0.94) were statistically significant (P<0.0001). Lithuanian version of the questionnaire was found to be responsive to clinical change. A statistically significant difference in the mean Sleep Apnea Quality of Life Index scores in the study group patients before and after the surgery was found in all daily functioning subdomains and social interactions domains.

Conclusions. Overall, the results of the present pilot study demonstrate that the Lithuanian version of Sleep Apnea Quality of Life Index is applicable for clinical purposes.

Introduction

Obstructive sleep apnea (OSA) defines with cessation of the airflow due to upper airway obstruction during sleep. This leads to sleep fragmentation and excessive daytime sleepiness. Number of arousals due to respiratory events at night has the most important role for daytime sleepiness (1). Questionnaires to assess excessive daytime sleepiness are developed and used routinely in clinical practice (2). They focus on sleepiness state and do not take into account the impact of this symptom on patient's life (3). Other daytime symptoms as cognitive impairment, decreased energy, and morning headaches are often not taken into the account when evaluating the OSA patient.

Generic Health-Related Quality of Life Instrument (HRQLI) has been used in OSA patients (4). However, the limited correlation between the impairment of quality of life and the severity of sleep apnea was observed (5). This reinforces the need for direct measurement of quality of life and health status in OSA patients (5).

The Calgary Sleep Apnea Quality of Life Index (SAQLI) is a disease-specific HRQLI developed by W. Flemons and M. Reimer in 1998 (3). SAQLI instrument is organized into four domains: A. Daily functioning (11 items), B. Social interactions (13 items), C. Emotional functioning (11 items), D. Symptoms (5 items). An additional domain E. Treatment-related symptoms (5 items) could be added in cases, when some active therapy is performed. The questionnaire is designed for administration by interview using Likert's scales with seven-response options. Color-coded

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cards are used so that subjects do not have to remember the response options (3). The SAQLI has been already validated in French and Chinese and was used in number of clinical studies (6–10). No specific HRQLI related to OSA has been adapted in Lithuanian to date. Therefore, the task of the present study was to arrange and test for its psychometric properties Lithuanian version of SAQLI (L-SAQLI) and assess quality of life among snoring and OSA patients before and after the treatment.

Material and methods

The study was approved by the Regional Ethics Committee of the Kaunas University of Medicine.

Cross-cultural adaptation of SAQLI

Cross-cultural adaptation of L-SAQLI was accomplished according to guidelines of cross-cultural adaptation of health-related quality-of-life measures by F. Guillemin *et al.* (1993) (11).

The two independent translations into Lithuanian language have been made by bilingual translators (T.B. – experienced physician and R.S. – professional translator) whose have the target language as their mother language. Then translations have been critically reviewed by authors and two back translations by bilingual translators totally blind to the original questionnaire (A.B. – professional translator experienced in medicine and I.R. – professional translator native English speaker). Then Expert Committee, consisting of authors, translators and language professional, assessed back translations for equivalence to original version. Semantic, idiomatic, experiential, and conceptual equivalences were discussed and pre-final version of questionnaire was developed for pretesting. Twenty-five persons from the target set completed questionnaire and were interviewed to inquiry that they thought was meant by each questionnaire item. Then pre-testing results were assessed at an Expert Committee, final corrections were made and a final version of L-SAQLI was accepted.

Study design and data collection

A prospective pilot study was carried out at Departments of Otorhinolaryngology and Pulmonology and Immunology of Kaunas University of Medicine between December 2005 and January 2008. In total, 36 patients suffering from socially disturbing snoring were included into the study. The age of the patients ranged from 23 to 64 years. All patients underwent complete full-night polysomnography (Alice 4 Sleep Diagnostic System, Healthdyne). According to apnea/hypopnea index (AHI), the sleep disorder was classified as follows: simple snoring (AHI<5), mild OSA (AHI 5–15), moderate OSA (AHI 16–30), and severe OSA (AHI>30) (12). Demographic data, symptoms, and comorbidity of the patients were recorded. Patients were excluded from the study if they had severe concurrent disease, which could affect their quality of life. Two sessions of temperature-controlled radiofrequency tissue ablation (RFTA) (CelonLab ENT system) was performed at the palatal and tong base (if was necessary) levels for all the patients enrolled into the study.

During initial examination, all the patients completed L-SAQLI questionnaire by an interview form. To test the intraindividual reliability (test-retest) of the L-SAQLI, 35 patients completed the same questionnaires 3 weeks after they had completed the questionnaires for the first time. Final examination of the patient was carried out after the period of 2 to 3 months after the second RFTA surgical intervention.

Statistical analysis

According to individual responses, mean scores of the L-SAQLI were calculated for the each domain. The L-SAQLI scores ranged from 1 to 7 with higher scores denoting better quality of life. Internal consistency of the L-SAQLI was evaluated by Pearson's correlation coefficients and by Cronbach's α. The test-retest reliability was measured by Pearson's correlations. Because of meaningful differences of the L-SAQLI items, exploratory factor analysis was performed separately for the each domain of the L-SAQLI to detect items not corresponding for the scale. The paired-sample *t* test was used to assess the responsiveness to clinical change of scores of the L-SAQLI at baseline and posttreatment.

Results

The demographic and clinical characteristics of the study group are summarized in Table 1. Severity of OSA in the tested group ranged from mild to moderate; just one patient presented with severe OSA.

Table 2 presents descriptive statistics of L-SAQLI domains. Descriptive statistics included the mean, standard deviation, median, range, and the percent scoring at the lowest possible value (floor) and the highest possible value (ceiling). Floor and ceiling effects were 0.0% for all L-SAQLI domains with the exception for secondary activities subdomain of daily functioning (ceiling effect 2.8%).

The Cronbach's α coefficients of internal reliability were above the standard (0.7 for groups) in all sub-

Table 1. **Demographic and clinical characteristics of the study group**

Characteristic	Study sample, n=36
Gender, n (%)	
Male	29 (80.6%)
Female	7 (19.4%)
Mean age (years)	41.1±9.7
Mean body mass index (BMI)±SD (kg/m^2)	28.7±4.2
Education level, n (%)	
Primary	2 (5.5%)
Secondary	3 (8.3%)
Further	11 (30.6%)
University	20 (55.6%)
Socioeconomic group, n (%)	
Worker	9 (25%)
Professional	24 (66.7%)
Student	1 (2.7%)
Pensioner	2 (5.6%)
Mean AHI±SD (points)	12.7±11.2

AHI – apnea/hypopnea index;
SD – standard deviation.

domains and domains: most important daily activity (A1–A4), 0.76; secondary activities (A5–A8), 0.82; general functioning (A9–A11), 0.77; social interactions (B), 0.88; and emotional functioning (C), 0.81. Test-retest correlation coefficients for each domains and subdomains ranged from 0.92 to 0.94: most important daily activity (A1–A4), 0.92; secondary activities (A5–A8), 0.92; general functioning (A9-A11), 0.94; social interactions (B), 0.94; emotional functioning (C), 0.93 (all P<0.0001).

The correlations between items inside the daily functioning (domain A) subdomains were positive and significant. Indeed, in the domains B and C (social interactions and emotional functioning) some insignificant and negative correlations were found between items B2–B8, B2–13, B4–B7, C4–C11, and C8–C10. According to exploratory factor analysis and correlation matrix results (results are not shown), items B2, B4, C10, and C11 were excluded from the evaluation of internal consistency. Table 3 shows corrected Cronbach α coefficients after eliminating negatively correlating items B2, B4, C10, and C11 (0.90 for domain B and 0.86 for domain C).

L-SAQLI was found to be responsive to clinical change. A statistically significant difference in the mean L-SAQLI scores in the group of OSA patients before and after surgery were found in all daily functioning subdomains and social interactions domains (P<0.05, Table 4).

Discussion

The cross-cultural adaptation process of the Lithuanian version of SAQLI was comprehensive and systematic according to generally accepted methodology (11, 13). The decisions on semantic and idiomatic equivalence were made, and final Lithuanian version after pretesting was elaborated.

L-SAQLI showed high test-retest reliability. Test-retest correlation coefficients for different domains varied from 0.92 to 0.94. Domain D of the SAQLI was excluded from the analysis because due to a very high variance of the symptoms, thus the domain D became very much individualized.

Similar test-retest reliability results in validation of French version of SAQLI study were achieved, while test-retest reliability of Chinese version of SAQLI validation studies remains unclear (6, 7). We agree that time lag between assessments to examine the stability of an instrument depends on a health condition under study (14). Too short a period might allow patients to recall their previous responses, and too long a period may allow a true change in their health status (15). We adopted 3-week test-retest

Table 2. **The L-SAQLI scores for the study group patients**

The SAQLI domains	No. of items	Mean±SD	Median	Range	Floor (%)	Ceiling (%)
A Daily functioning:						
A1–A4 Most important daily activity	4	4.5±1.3	4.5	1.5–6.8	0.0	0.0
A5–A8 Secondary activities	4	4.4±1.3	4.5	2.3–7.0	0.0	2.8
A9–A11 General functioning	3	4.6±1.2	4.7	2.3–6.7	0.0	0.0
B Social interactions	13	4.9±1.1	4.8	2.4–6.8	0.0	0.0
C Emotional functioning	11	4.9±0.9	5.0	3.1–6.3	0.0	0.0

SD – standard deviation.

Table 3. **Internal consistency of the SAQLI after eliminating items B2, B4, C10, and C11**

The SAQLI domains	No. of items	Inter-item correlations			Cronbach's α
		mean r	min.	max.	
A Daily functioning					
A1–A4 Most important daily activity	4	0.43	0.25	0.68	0.76
A5–A8 Secondary activities	4	0.52	0.39	0.91	0.82
A9–A11 General functioning	3	0.54	0.45	0.63	0.77
B Social interactions	10	0.45	0.22	0.79	0.90
C Emotional functioning	9	0.41	0.08	0.70	0.86

Mean r, min., max. – mean Pearson correlations, minimal and maximal values inside the designed domains.

Table 4. **Comparison of the L-SAQLI mean scores before and after surgery (paired samples t test)**

The L-SAQLI domains	Before surgery mean±SD	After surgery mean±SD	Mean difference	t test	P value
A Daily functioning:					
A1–A4 Most important daily activity	4.5±1.3	5.1±1.1	–0.59	–2.6	0.014
A5–A8 Secondary activities	4.4±1.3	5.0±1.2	–0.56	–3.0	0.005
A9–A11 General functioning	4.6±1.2	5.2±1.2	–0.55	–2.3	0.025
B Social interactions	4.9±1.1	5.2±1.0	–0.34	–2.5	0.019
C Emotional functioning	4.9±0.9	5.2±1.0	–0.24	–1.7	0.099

m – mean score of the L-SAQLI; SD – standard deviation.

period while these intervals at the mentioned above validation studies are not known. The comparison of the results of different studies is cumbered until the test-retest interval is not standardized and different study samples to access test-retest reliability are used.

Good construct validity of the questionnaire requires that items inside the designed domain should correlate positively and significantly. Analyzing internal consistency inside daily functioning (domain A) subdomains, these conditions were satisfied. Whereas some insignificant and negative correlations were found in social interactions and emotional functioning domains, we consider that the rather small study group is a limitation of pilot study. We will consider elimination of some items or the subscaling of domains B and C in the Lithuanian translation of the SAQLI if the problems after increment of study sample persist.

Statistics of responsiveness of L-SAQLI were calculated as the mean change of SAQLI scores before and after RFTA surgery. Statistically significant differences among the mean L-SAQLI scores before and after surgery in our study group were found in the daily functioning and social interactions domains ($P<0.05$), while in validation studies of Chinese and French SAQLI versions, the mean scores in all domains were found to be significantly increased after the treatment (6, 7). Statistical techniques with their focus on P values assure that the observed statistically significant changes are likely to not be due to chance (16). The results, however, depend on sample size and variation (16). Although we did not observe the statistically significant difference in the mean scores in domain C before and after the RFTA treatment, the results of the present study showed a tendency towards improvement of the quality of life of the tested patients. Whereas in similar validation studies of Y. Lacasse, C. Godbout, F. Series (2002) and Y. W. Mok, L. K. Lam, B. Lam, M. T. Cheung, L. Yam *et al.* (2004), the given study sample mainly consisted of moderate to severe OSA patients; therefore, such circumstance could determine the higher HRQLI changes after the adequate therapy (6, 7).

Although the patients with moderate to severe OSA are mostly included in quality-of-life studies, some studies have demonstrated a marked impairment of the quality of life in patients with even mild OSA after therapy (4). Just few studies examined change of HRQL after minimally invasive OSA surgery (17, 18). One of these studies found similar HRQL changes in

quality of life after surgical or continuous positive airway pressure (CPAP) treatment in groups of mild to moderate OSA patients while measured by SF-36 quality-of-life questionnaire (17). Supposedly, the disease-specific HRQL instruments are more responsive to generic instruments because they focus on the areas of function that are relevant to that particular condition (19). Future studies could clarify the situation.

Conclusions

The Lithuanian version of Sleep Apnea Quality of Life Index shows strong test-retest reliability and acceptable internal consistency. The Lithuanian version of Sleep Apnea Quality of Life Index was found to be responsive to clinical change. Overall, the results of the present pilot study demonstrate that the Lithuanian version of Sleep Apnea Quality of Life Index is applicable for clinical purposes.

Miego apnėjos gyvenimo kokybės indekso klausimyno lietuviškosios versijos psichometrinės savybės (bandomasis tyrimas)

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Raktažodžiai: obstrukcinė miego apnėja, Kalgario miego apnėjos gyvenimo kokybės indeksas, knarkimas, radiodažninė termoabliacija.

Santrauka. *Tyrimo tikslas.* Parengti lietuviškąją Kalgario miego apnėjos gyvenimo kokybės indekso klausimyno versiją, ištirti knarkiančių ir obstrukcinės miego apnėjos sindromu sergančiųjų gyvenimo kokybę iki ir po gydymo bei įvertinti klausimyno psichometrines savybes.

Medžiaga ir metodai. Klausimyno lietuviškosios versijos kultūrinė adaptacija atlikta pagal tarptautines rekomendacijas. Į studiją įtraukėme 36 (29 vyrai ir 7 moterys, amžiaus vidurkis 41,1±9,7 metų) knarkimu ir obstrukcine miego apnėja besiskundžiančius ligonius. Visiems ligoniams atlikta stacionari polisomnografija (vidutinis apnėjų–hiponėjų indeksas =12,7±11,2). Ligoniams taikytos dvi minkštojo gomurio ir liežuvio šaknies (pagal indikacijas, jei reikėjo) radiodažninės termoabliacijos sesijos. Kalgario miego apnėjos gyvenimo kokybės indekso klausimyno lietuviškąją versiją ligoniai užpildė interviu forma prieš pradedant gydymą ir praėjus dviem trims mėnesiams nuo antrosios radiodažninės termoabliacijos. Klausimyno stabilumui pakartotinio testavimo metodu nustatyti, praėjus trims savaitėms nuo pirmojo tyrimo, pakartotinai ištirti 35 ligoniai.

Rezultatai. Nustatytas labai stiprus klausimyno skyrių vidinis nuoseklumas. Visų skyrių ir poskyrių Kronbacho alfa rodikliai buvo didesni nei 0,7. Nustatytas labai stiprus testo-retesto stabilumas (atskiruose skyriuose nuo 0,92 iki 0,94). Vidutiniai lietuviškojo Kalgario miego apnėjos gyvenimo kokybės indekso įverčiai iki ir po gydymo statistiškai reikšmingai skyrėsi visuose kasdienės veiklos poskyriuose ir socialinių ryšių skyriuje ($p<0,05$).

Išvados. Lietuviškoji Kalgario miego apnėjos gyvenimo kokybės indekso klausimyno versija yra tinkama klinikiniam knarkiančių ir obstrukcinės miego apnėjos sindromu sergančių ligonių gyvenimo kokybės tyrimui.

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