Validation of the Sinhala Berlin and STOP-Bang questionnaires to detect obstructive sleep apnoea risk among antenatal women in Sri Lanka

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Validation of the Sinhala Berlin and STOP-Bang questionnaires to detect obstructive sleep apnoea risk among antenatal women in Sri Lanka

Priyadarshanie MN[1], Waas MDIA[2], Goonewardena CSE[3], Balasuriya A[4], Senaratna BCV[5†], Fernando DMS[6†]

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Abstract

Introduction: Screening can facilitate early detection and management of obstructive sleep apnoea (OSA) during pregnancy and improve pregnancy outcomes. Our aim was to determine the validity of the Sinhala translation of the Berlin and STOP-Bang questionnaires to detect the OSA risk among Sri Lankan antenatal women.

Methods: Berlin and the STOP-Bang questionnaires were translated to Sinhala language using the standard translation/ back-translation method. Face, content, and consensual validity of the Sinhala versions of Berlin (Berlin-S) and STOP-Bang (STOP-Bang-S) questionnaires were determined through a modified Delphi process conducted among respiratory physicians. These validated versions were administered to 200 antenatal women at selected antenatal clinics. The exploratory and confirmatory factor analyses (EFA and CFA) were performed. Internal consistency was assessed. Test-retest reliability and Inter-interviewer reliability for these questionnaires were assessed using Cohen's kappa (k) and intra class correlation coefficient (ICC) values, respectively.

Results: Berlin-S and STOP-Bang-S showed good content, consensual and face validity. The EFA for Berlin-S confirmed a three-factor model compatible with the original instrument but CFA confirmed a one-factor model. The EFA for STOP-Bang-S confirmed a two-factor model. The CFA confirmed a one-factor model that was compatible with the original factor structure. The internal consistency of Berlin-S and STOP-Bang-S were satisfactory. Test-retest reliability of Berlin-S and STOP-Bang-S were high for Berlin-S categories (k 0.828 [95% CI: 0.65-1.00]) and STOP-Bang-S score (ICC 0.982 [95% CI: 0.954-0.993]) respectively.

The Cohen's kappa value for the Inter-interviewer reliability of Berlin-S categories was 1.00 (95% CI: 1.00-1.00) and the ICC of STOP-Bang-S total score were 0.992 (95% CI: 0.960-0.994).

Conclusions: The Sinhala versions of Berlin and STOP-Bang questionnaires are valid and reliable tools to screen for OSA risk among antenatal women in Sri Lanka.

Key words: OSA, screening, Berlin, STOP-Bang, antenatal women, Sri Lanka

[1]*Department of Nursing and Midwifery, Faculty of Allied Health Sciences, General Sir John Kotelawala Defence University, Rathmalana, Sri Lanka,* [2]*Department of Psychiatry, Faculty of Medical Sciences, University of Sri Jayewardenepura, Nugegoda, Sri Lanka,* [3]*Department of Community Medicine, Faculty of Medical Sciences, University of Sri Jayewardenepura, Nugegoda, Sri Lanka,* [4]*Department of Public Health, Faculty of Medicine, Kotelawala Defence University, Rathmalana, Sri Lanka.* [5]*Non-Communicable Diseases Research Centre, University of Sri Jayewardenepura, Nugegoda, Sri Lanka,* [6]*Department of Physiology, Faculty of Medical Sciences, University of Sri Jayewardenepura, Nugegoda, Sri Lanka.*

[†] *Equal contribution*

Correspondence: MNP, e-mail: sharaine@sjp.ac.lk

https://orcid.org/0000-0002-6586-1034

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Introduction

Pregnancy is a vulnerable period for development or worsening of obstructive sleep apnoea (OSA)[1] that could be continuation or worsening of pre-existing OSA or new onset OSA caused by physiological changes specific to the pregnancy (gestational OSA).[1] This gestational OSA results from oedema of the upper airway and higher negative upper airway pressure that results from respiratory-driven changes caused by elevated oestrogen and progesterone levels.[1] The prevalence of gestational OSA which is around 10.5% in early pregnancy increases during second and third trimesters of the pregnancy becoming as high as 26% in the third trimester.[1-3]

Limited evidence suggests that OSA during pregnancy is associated with maternal, foetal and neonatal morbidities.[4] OSA was reported to be associated with maternal complications like cardiomyopathy, congestive heart failure, pulmonary embolism and metabolic disorders including gestational diabetes mellitus (GDM), pregnancy induced hypertension(PIH),[4] maternal obesity, and preeclampsia,[5] and to increase the incidence of elective and emergency caesarean deliveries and assisted vaginal deliveries.[6] Adverse foetal/ neonatal outcomes include foetal growth restriction, foetal hypoxia, neonatal hyperbilirubinemia,[7] low APGAR score,[1] pre-term births,[6,8] low birth weight (LBW),[9] and stillbirth/ perinatal death and neonatal intensive care unit (NICU) admissions.[6]

These evidences suggest that early detection and management of OSA during pregnancy are likely to improve pregnancy outcomes. The gold standard for diagnosis of OSA is polysomnography[10] but performing this is not always feasible due to cost and logistical constraints.[11] Therefore, several standard validated questionnaires are used in epidemiological studies and in clinical practice to identify those who are at high risk for OSA.[12,13] Berlin questionnaire and STOP-Bang questionnaire are two widely used such questionnaires.[11,14] The sensitivity and specificity of Berlin questionnaire are 90% and 80%, respectively, and of STOP-Bang questionnaire are 82.5% and 90%, respectively.[15] These questionnaires have performed well in screening for OSA-risk during pregnancy.[16] Good validity and reliability have been reported for several translations of STOP-Bang questionnaire such as the Slovene version,[17] the Spanish version,[18] the Portuguese version,[19] and Arabic version.[20] The translations of Berlin questionnaire that showed good validity, reliability and the cross cultural adaptability[21] include the Malaysian translation (Berlin-M),[22] the Thai translation,[14] the Hindi translation,[23] the Danish translation[24] and the Portuguese translation.[25]

In Sri Lanka, no specific information is available on OSA prevalence in antenatal women but this is likely to be high as OSA-risk for Sri Lankan women in general is reportedly 18.3%.[26] Sri Lankan antenatal women are not routinely screened for OSA, one reason for this being the lack of cross-culturally adapted screening instruments. As OSA during pregnancy is likely to be high and reportedly associated with adverse maternal and foetal outcomes, screening for OSA during pregnancy may be useful to prevent some of these adverse outcomes. Given this backdrop, a valid and a reliable questionnaire to screen for OSA-risk among antenatal women in Sri Lanka is a current need. Our aim was to determine the validity of the Sinhala translation of the Berlin and STOP-Bang questionnaires to detect the OSA risk among Sri Lankan antenatal women.

Methods

Translation and Validation of both Berlin and STOP-Bang questionnaires were done in parallel. The Berlin and STOP-Bang questionnaires were translated to Sinhala language. The content, consensual, face and construct validity types were determined in both Berlin and STOP-Bang questionnaires.

The Berlin questionnaire consists of three categories that collectively contain ten questions on OSA symptoms and information on height and weight. Category 1 contains five questions on snoring and cessation of breathing, category 2 contains four questions on excessive daytime sleepiness and category 3 has one question on hypertension and information on height and weight to calculate BMI. Positive scores in 2 or more categories suggest that the respondent has a high risk for OSA.[27,28] Sinhala translated Berlin questionnaire is given in the online supplement (Box S1).

STOP-Bang questionnaire has eight items that are answered as yes/no. Those in the STOP-Bang component includes “Do you **s**nore loudly (louder than talking or loud enough to be heard through closed doors)”, “Do you often feel **t**ired, fatigued, or sleepy during daytime?”, “Has anyone **o**bserved you stop breathing during your sleep?” and “Do you have or are you being treated for high blood **p**ressure?”. The Bang component consists of four anthropometric and demographic queries, namely, **b**ody mass index (BMI) over 35kg/m^2, **a**ge over 50 years, **n**eck circumference

equal or more than 40cm, and male **g**ender. Positive response to each item scores 1 and a negative response scores 0. The total score ranges between 0 and 8. A score 3 or more is considered as indicating a high risk for OSA.[29] The STOP-Bang is considered superior to other questionnaires in detecting separately mild, moderate, and severe OSA and can be administered in less than five minutes.[29] Sinhala translated STOP-Bang questionnaire is given in the online supplement (Box S2).

Translation of Berlin and STOP-Bang questionnaires into Sinhala language

Translation and validation of these questionnaires were carried out according to the World Health Organization (WHO) guidelines on the process of translation and adaptation of instruments[30].

Steps in translation of the Berlin and STOP-Bang questionnaires are summarized in Figure 1.

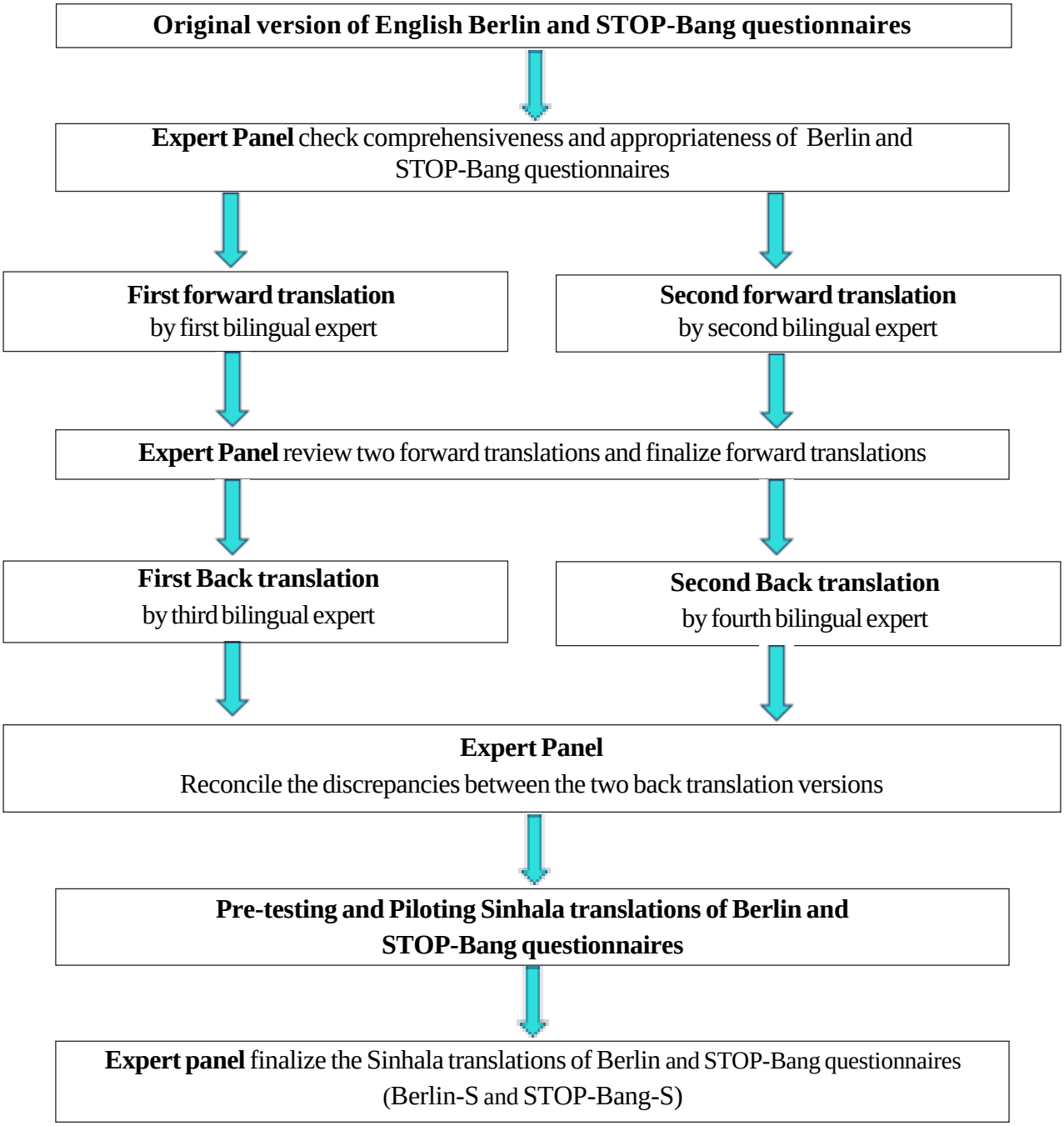

Figure 1. Translation procedure of Sinhala translation of Berlin and STOP-Bang questionnaires.

Firstly, the English version of Berlin and STOP-Bang was reviewed by a local expert panel to determine its comprehensiveness and appropriateness for local use. This panel consisted of three consultant respiratory physicians, two obstetricians and three community physicians. All items of Berlin and STOP-Bang were marked as suitable for screening for OSA in antenatal women by this expert panel. Secondly, two independent bi-lingual experts translated Berlin and STOP-Bang separately into Sinhala. These two Sinhala versions of each questionnaire were compared by an expert panel, which included a consultant respiratory physician and two community physicians, and inadequacies in terminology of the translation and any discrepancies between two Sinhala versions were resolved.

These first drafts of the Sinhala versions of Berlin and STOP-Bang were back-translated into English by two other independent bi-lingual translators who were blinded to the English Berlin and STOP-Bang. Two back-translations of each questionnaire were reviewed by an expert panel, which included two consultant respiratory physicians, two obstetricians and two community physicians who rated all items as correctly translated. This panel provided consensual approval on the preservation of original English meaning of all items of the Berlin and the STOP-Bang in their Sinhala versions.

Validation of Sinhala translations of Berlin and STOP-Bang questionnaires

The face and content validity of the translated questionnaires were determined using modified Delphi technique.[31] Eight experts consisting of three consultant respiratory physicians, three obstetricians, and two consultant community physicians were invited to participate in consensus development. They assessed the Sinhala translations for the face validity, content, the appropriateness of the words used and the cultural relevance, and the translation equivalence to English version of each item. After conducting three modification rounds with experts, final version was granted 100% consensual approval by all experts included in the panel. The resulting version was used in cognitive interviews. Delphi procedure of validating Berlin-S and STOP-Bang-S is given as an online supplement (Box S3).

These cognitive interviews conducted with 20 antenatal women aged 18 years of age or older attending antenatal clinics (ANCs) of De Soysa Maternity Hospital for Women (DMH), a major tertiary care hospital in Colombo District, provided further conceptual validation of Sinhala translations of Berlin and STOP-Bang. During these face to face interviews, their comprehension of literal and conceptual meaning of the questions in the two translations and clarity and suitability of wording used were probed and verified. Minor revisions made were referred to the expert panel and their confirmations were obtained. These final confirmed Sinhala versions of Berlin and STOP-Bang questionnaire (Berlin-S and STOP-Bang-S) were used in subsequent pilot testing and factor analyses.

Pilot testing

Both questionnaires were piloted among twenty women 18 years of age or older, attending community ANCs (Divulpitiya antenatal clinic, Boralesgamuwa MOH area) to identify any practical constraints in administering questionnaires in such clinics where any antenatal screening is likely to take place, including the convenience of administration, participants' problems when responding, time required to conduct study and any other issues.

Data collection for factor analyses and reliability assessment

Berlin-S and STOP-Bang-S were administered to antenatal women age at least 18 years attending ANCs of Boralesgamuwa, Piliyandala, Kesbewa and Maharagama Medical Office of Health (MOH) areas to ascertain factor structure and reliability of these questionnaires. They were recruited irrespective of the trimester of pregnancy. Any woman who participated in the pre-test and the pilot study, and those with disabilities such as hearing difficulty, visual and speaking problems were excluded.

According to Tabachink and Fidell (2013), the sample size required for this component was to be 5-10 times the number of items in the instrument to be validated[32]. As both scales were validated in the same population, 100 antenatal women were taken as the sample size to perform EFA and another 100 antenatal women to perform CFA.

Using the clinic register as the sampling frame for each clinic, eligible women were recruited using a systematic random sampling with a sampling interval of 3 until the required sample of 200 women were selected. After providing informed written consent, the recruited antenatal women responded to Berlin-S and

STOP-Bang-S which were administered by a trained graduate nurse.

To determine the test-retest reliability the two questionnaires were re-administered to 20 antenatal women 14 days after the first interview by the same interviewer. To determine the inter-interviewer reliability, the same questionnaires were re-administered by a different interviewer 14 days after the first interview to 20 antenatal women.

Statistical analysis

Descriptive data on participants are described as numbers and percentages or means and standard deviations (SDs). To examine the construct validity of Berlin-S and STOP-Bang-S, the relevant procedures were conducted for each questionnaire separately. Sample adequacy and suitability for factor analysis were conducted using Kaiser-Meyer-Olkin (KMO) test and Bartlett's test, respectively.

Factor extraction was done using principal component analysis (PCA) for exploratory factor analysis (EFA) with oblique rotation method which was suggested to be used in correlated variables.[33] The correlation value of 0.4 was considered as the cut off factor loading which is mandatory to include in a factor structure.[34]

Confirmatory factor analysis (CFA) was performed to confirm the construct of factor structure, after ensuring that the required assumptions were fulfilled. LISREL 10.3 software was used for CFA. The robust maximum likelihood method was employed to evaluate model parameters. Furthermore, construct validity was evaluated using CFA.

Additivity test was used to check whether the scale was on an additive scale. Factor model was evaluated for each questionnaire. The indices used to determine the model fit included the absolute fit indices, relative fit indices and parsimony fit indices. Absolute fit indices were chi-squared test, root mean squared error of approximation (RMSEA), goodness of fit index (GFI), adjusted goodness of fit index (AGFI) and standardized root mean squared residual (SRMR). Relative fit indices were comparative fit index (CFI) and non-normed fit index (NNFI), while parsimony fit indices were parsimony goodness of fit index (PGFI) and parsimonious normed fit index (PNFI).

RMSEA values below 0.05 indicate a good fit to data, values between 0.05 and 0.08 an acceptable fit, values between 0.08 and 0.10 a marginal fit and values above 0.10 a poor fit[35,36]. For the CFI and NNFI, values above 0.95 indicate a good fit[37] to data while for GFI and AGFI, over 0.90 indicate a good fit.[38]

The data were divided randomly into two equal subsamples; one subsample was used to perform EFA (n=100), and the other was used to perform CFA (n=100). Internal consistency of Berlin-S and STOP-Bang-S was measured using CR value and Cronbach's alpha value. The CR value, and ranged between 0.70 to 0.90 were considered as a good reliability and[39] Cronbach's alpha coefficients value equal or higher than 0.70 were considered as acceptable reliability measures.[40] In addition, the test-retest reliability and inter-interviewer reliability for Berlin-S categories was assessed using Cohen's kappa (k) and that of STOP-Bang-S score using, intra-class correlation coefficient (ICC).

Ethics approval and consent to participate

Ethical approval was obtained from the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura (ERC ref. No: 31/19 24th October 2019). All participations were voluntary and participants' identities were kept strictly confidential. Informed written consent was obtained from all participants.

Results

After successful translation of Berlin and STOP-Bang questionnaires into Sinhala, the expert panel consisting of 8 members confirmed face, content, and consensual validity of Berlin-S and STOP-Bang-S. Further conceptual validity was confirmed during cognitive interviews with antenatal women. The mean age (± SD) of 200 antenatal women who provided data for factor analyses was 29.6 (±5.3) years. Most (66%) of them had completed primary education and 55% were multiparous (Table 1). Majority of them (81%) were in second or third trimesters of pregnancy.

Table 1. Basic characteristics of the antenatal women (n=200) who provided data for factor analyses

Variable	*Frequency(n)*	*Percentage (%)*
Age (Years)		
18-23	24	12.0
24-29	70	35.0
30- 35	86	43.0
36-41	20	10.0
Level of education		
No schooling	4	2.0
Primary	132	66.0
Secondary	64	32.0
Monthly income Level (SLR)		
0-20000	40	20.0
20001-40000	104	52.0
40001-60000	32	16.0
60001-80000	4	2.0
80001-100000	12	6.0
100001 and above	8	4.0
Pregnancy and childbirth status		
First pregnancy	90	45.0
Living child 1	80	40.0
Living children 2	20	10.0
Living Children 3	6	3.0
Living Children 4	2	1.0
Living Children 5	2	1.0
Trimester in current pregnancy		
Trimester 1	38	19.0
Trimester 2	84	42.0
Trimester 3	78	39.0

Exploratory factor analysis

KMO test value for sampling adequacy for Berlin-S was 0.667. Bartlett's test of sphericity was significant (χ^2=532.284; df 55; p<0.01).

As per the three-factor model analysis, the total variance obtained in Berlin-S was 63.1% (n=100). Factor structure with the individual factor loading values is given in Table 2.

Table 2. Factor structure of the STOP-Berlin-S

Items of Berlin questionnaire	*Factors*		
	1	*2*	*3*
1. Snoring and cessation of breathing (Category 1)			
1. Do you snore?	0.954		
2. Your snoring is:	0.918		
3. How often do you snore?	0.833		
4. Has your snoring ever bothered other people?	0.773		
5. Has anyone noticed that you quit breathing during your sleep?	0.663		
2. Symptoms of excessive daytime sleepiness (Category 2)			
6. How often do you feel tired or fatigued after your sleep?		0.833	
7. During your waking time, do you feel tired, fatigued or not up to par?		0.782	
8. Have you ever fallen asleep while waiting in a line, If yes, how frequently?		0.711	
9. Have you ever fallen asleep while watching television at your home during daytime? If yes, how frequently?		0.611	
3. BMI and hypertension (Category 3)			
10. Do you have high blood pressure?			0.665
11. Your Body mass index **(BMI)** over 30kg/m^2			0.758

Cattell's screen test was used to show the eigenvalues of three factor model of the Berlin-S (Figure 2). After considering the eigen values of all factors, number of factors with eigen value greater than 1 can be considered to calculate number of factors in the factor structure.

In the factor structure of Berlin-S; Eigen value of factor 1, 2 and 3 was 3.529, 2.249 and 1.165. According to the eigen values indicated in the scree plot (in Berlin-S), only three factors' eigen values were greater than 1.

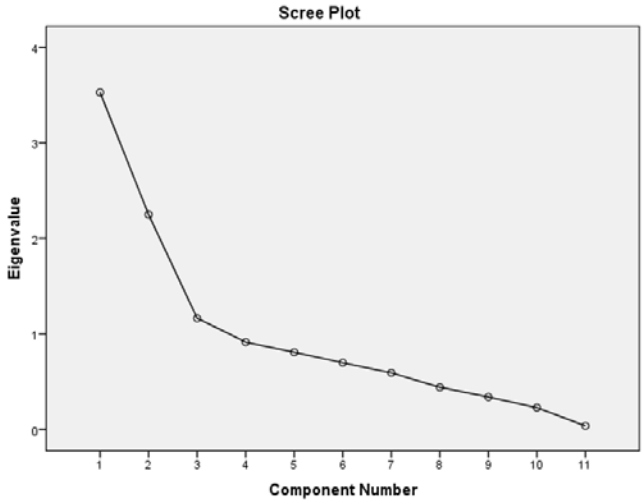

Figure 2. Scree plot showing the eigenvalues of the factors representing the items from the Berlin-S for antenatal women.

According to the EFA done for the items of the STOP-Bang questionnaire, the KMO test value as 0.662. Bartlett's test of sphericity was significant (χ^2=150.767; df 15; p<0.01). The two-factor model obtained a total variance of 59.7% (n=100). Factor structure with the individual factor loading values is given in Table 3. Eigenvalues of two factor model of the STOP-Bang-S generated using Cattell's scree test is shown in Figure 3. In the factor structure of STOP-Bang-S; Eigen value of factor 1 and 2 was 2.527, and 1.057. According to the eigen values indicated in the scree plot (in STOP-Bang-S), only two factors' eigen values were greater than 1.

Table 3. Factor structure of the STOP-Bang-S

Items of Bang questionnaire	*Factors*	
	1	*2*
1. Snore, tired, observed and blood pressure		
1. Do you snore loudly?	0.879	
2. Do you often feel tired, fatigued, or sleepy during daytime?	0.831	
3. Has anyone observed you stop breathing during your sleep?	0.788	
4. Do you have or are you being treated for high blood pressure?	0.435	
2. BMI and Neck circumference		
1. Body mass index (BMI) over 35kg/m^2		0.813
2. Neck circumference over 40cm		0.638

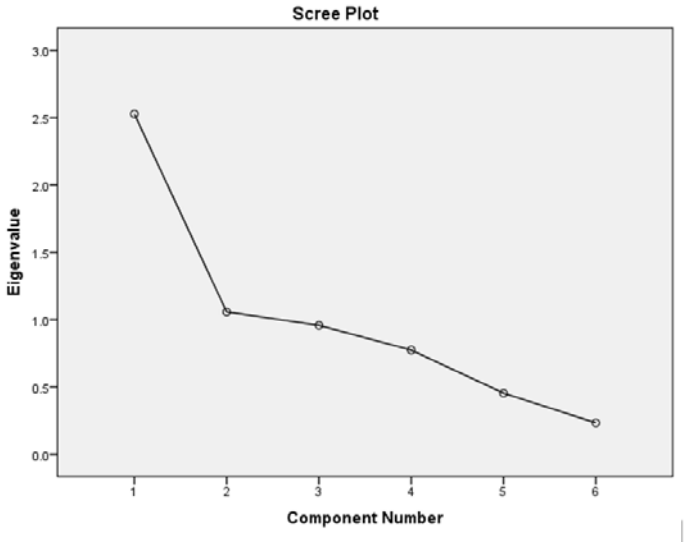

Figure 3. Scree plot showing the eigenvalues of the factors representing the items from the STOP-Bang-S for antenatal women.

Confirmatory factor analysis

For Berlin-S, one factor model was found to have better model fit indices as per the combinational rule generated by Hu and Bentler (Hu and Bentler,1999). One factor model for Berlin-S showed a Chi-squared value of 138.540 (df = 9; p < 0.005). CFI of 1.000 and SRMR value of 0.0890 for the model fit. The other fit indices were as follows; GFI = 0.819, AGFI = 0.686, NNFI = 0.806, PGFI = 0.473 and PNFI = 0.603. One-factor model of Berlin-S was closer to the good fit indices in each absolute, relative, and parsimony fit indices.

The fit indices obtained in the CFA for STOP-Bang-S indicated that the data fit the one factor model perfectly. The one factor model gave a Chi-squared value of 17.049 (df = 9; p< 0.005). The RMSEA value was 0.085 while SRMR, GFI and AGFI were 0.0797, 0.949 and 0.880 respectively. CFI, NNFI, PGFI and PNFI were 0.824, 0.707, 0.407 and 0.432 respectively.

The one-factor model was closer to the good fit indices in each absolute, relative, and parsimony fit indices. Fit indices for Berlin-S and STOP-Bang-S according to different factor models are given in Table 4.

Table 4. Fit indices for confirmatory factor models of the sample (n=100)

Indices	*Reference range*	*Berlin-S*			*STOP-Bang-S*	
		One factor model	*Two factor model*	*Three factor model*	*One factor model*	*Two factor model*
Chi-square value		138.540	38.699	36.261	17.049	16.170
Degrees of freedom (DF)		9	43	41	9	8
P value	<0.05	<0.05	P=0.6582	P=0.6810	<0.05	<0.05
RMSEA (90%CI)	<0.08	0.1765 (0.148; 0.205)	0.0283 (0.0; 0.0566)	0.0279 (0.0; 0.0559)	0.085 (0.00879; 0.163)	0.0964 (0.0208; 0.172)
GFI	>0.90	0.819	0.926	0.930	0.949	0.951
AGFI	>0.90	0.686	0.887	0.887	0.880	0.879
SRMR	<0.08	0.0890	0.0770	0.0779	0.0797	0.0774
CFI	>0.95	1.000	1.000	1.000	0.824	0.822
NNFI	>0.95	0.806	1.052	1.060	0.707	0.666
PGFI	>0.5	0.473	0.603	0.578	0.407	0.362
PNFI	>0.5	0.603	0.594	0.578	0.432	0.391

RMSEA-Root Mean Square Error of Approximation, GFI-Goodness of Fit Index, AGFI-Adjusted Goodness of Fit Index, SRMR-Standardized Root Mean Square Residual, CFI-Comparative Fit Index, NNFI-Non-Normed Fit Index, PGFI-Parsimony Goodness of Fit Index, PNF-Parsimonious Normed Fit Index

Validity and reliability of the Berlin-S and the STOP-Bang-S

Cronbach's alpha value for the internal consistency of the categories 1 and 2 of Berlin-S were 0.711 and 0.718, respectively. The CR value for the Berlin-S was 0.92 with average variance extract value (AVE) value of 0.69.

Cronbach's alpha value for the internal consistency of STOP-Bang-S was 0.722. Composite reliability value for STOP-Bang-S was 0.84 with AVE value of 0.57 (Table 5).

The Cohen's kappa value for the test-retest reliability of Berlin-S categories was 0.83 (95% CI: 0.65-1.00) and the ICC of STOP-Bang-S total score were 0.982 (95% CI: 0.954-0.993).

Inter-interviewer reliability for Berlin-S categories 1.00 (95% CI: 1.00-1.00) and STOP-Bang-S score (ICC 0.992 [95% CI: 0.960-0.994]) respectively.

Discussion

Our aim was to determine the validity of the Sinhala translation of the Berlin and STOP-Bang questionnaires to detect the OSA risk among Sri Lankan antenatal women. During the standard translation process that we used, the conceptual equivalence between the original and the Sinhala version of Berlin and STOP-Bang questionnaires were preserved and the content, consensual and face validity of Berlin-S and the STOP-Bang-S were confirmed by the clinical experts. The construct validity of these questionnaires was good. The internal consistency and the test-re test and inter-rater reliability were also good.

Forward and back translation processes that we used is similar what was used in previous translations in other countries.[22-25,41-43 17,18,22,44,45] The modified Delphi method that we used was also similar to what was done before,[46] and provided 100% agreement by the experts regarding validity and cultural acceptability of the two translations.

To the best of our knowledge, this is the first study to report the construct of Berlin evaluated using CFA, the best method of evaluating the construct of a tool.[47] CFA showed that one factor structure best fitted both translations. CFA done for STOP-Bang questionnaire, in a previous study conducted in Saudi Arabia reported that two factor structure as the best fitting the STOP-Bang questionnaire.[20] EFA was also conducted for Berlin questionnaire which gave a three factor structure in comparison to a previous study done in Thailand reporting a four factor structure for Berlin questionnaire.[41] The discrepancy of factor structure may be due to the changes of clinical presentation in OSA among two different communities.

The internal consistency of the Berlin-S and the STOP-Bang-S was assessed using CR value and Cronbach's alpha value. The satisfactory Cronbach's alpha value obtained for the current study is similar to the original study[29] conducted to validate Berlin questionnaire and the validation of Thai Berlin questionnaire.[41] A good Cronbach's alpha value for STOP-Bang-S was observed in the current study and it is higher than Portuguese STOP-Bang and Greek STOP-Bang. However, similar to the Cronbach's alpha value reported in Arabic STOP-Bang questionnaire. In addition, to the best of our knowledge, this is the first to report a high internal consistency using CR value

Table 5. Internal consistency, composite reliability (CR), and the average variance extracted (AVE)

	Internal consistency	*Composite reliability*	*Average variance extracted*
Berlin-S Items 2,3 and 5	0.711	0.92	0.69
Berlin-S Items 7,8 and 9	0.718		
STOP-Bang-S	0.722	0.84	0.57

with high AVE value. We have conducted CFA and assessed for CR value. Therefore, the factor construct is confirmed to reliable as reliability was assessed using two standard methods.

A high test retest reliability, k value reported for the Berlin-S categories is similar to the test retest reliability reported in Malaysian version of Berlin categories[22] while a high test retest reliability, ICC value reported in the STOP-Bang-S score is similar to the test retest reliability reported in Arabic version of STOP-Bang questionnaire.[20] However, to the best of our knowledge, this is the first study to report a high inter-interviewer reliability.

OSA is known to contribute to adverse pregnancy outcomes. Thus, detecting and treating antenatal OSA may improve pregnancy outcomes.[13] The validated Berlin-S and STOP-Bang-S can be used for this purpose. Since OSA risk is also increasing in the general population, these two validated tools can be adapted to screen for OSA in the general population as well.

The main strength of our study is that we used the standard methods for translation and validation, and that experts provided 100% agreement on its validity and cultural adaptation. To the best of our knowledge, ours is the first to report the construct validity of both Berlin-S and STOP-Bang-S questionnaires using the EFA and CFA. In addition, the current study is the first to report internal consistency using both methods; Cronbach's alpha, CR values.

The total variance explained percentage of Berlin-S was at a satisfactory level (above 60%), and the total variance explained percentage of STOP-Bang-S was less than 60%. However, the value was 59.76%, which is closer to 60%. According to the available evidence, it was reported that 60% of the total variance (and in some instances even less) also can be considered as satisfactory level of total variance explained.[39]

Our study has a few limitations. Firstly, we were unable to check the criterion validity as ethical approval was not granted for antenatal women to undergo sleep studies simply for the validation purpose. Therefore, future studies are recommended to detect criterion validity of Berlin-S and STOP-Bang-S among non-pregnant Sri Lankan population.

The study was conducted among antenatal women from selected MOH areas in Colombo district of Sri Lanka who may not represent the general population in Sri Lanka. Although this may seem a limitation, it is unlikely that the comprehension of literal and conceptual meaning of the questions in Berlin-S and STOP-Bang-S would differ in other Sinhala-speaking populations in Sri Lanka.

Conclusion

The Sinhala version of both Berlin and STOP-Bang questionnaires are valid and reliable tools to detect high risk for OSA during pregnancy but Berlin-S seems more useful than STOP-Bang-S given its better validity and reliability parameters. Both are suitable tools to be used in clinical practice and in research and could be useful to screen for OSA in routine antenatal care. Establishing criterion validity of both questionnaires in the Sri Lankan general population is a need. If a national level screening is envisaged, it is important to translate both questionnaires to Tamil language, which is used by some minority groups in Sri Lanka.

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Conflicts of Interests

The authors declare that they have no conflicts of interests.

Criteria for authorship

MNP collected and analyzed data, interpreted results and was responsible for manuscript writing. MDIAW contributed to writing the discussion. DMSF and BCVS as senior authors contributed by conceptualizing and developing the study, interpreting results and in revising the manuscript. CSEG contributed to implementing the study and revising the manuscript. AB contributed to interpreting results. All authors read and approved the final version of the manuscript. All authors are guarantors of the paper.

Sinhala translated Berlin Questionnaire (BOX S1)

වයස : ..... ස්ත්‍රී/පුරුෂ : .....

උස : ..... බර : .....

1. ඔබ නින්දේදි ගොරවයිද?

a. ඔව් b. නැත c. නොදනී

2.ඔබේ නින්දේදි ගෙරවීම:

a හුස්ම ගන්නා ශබ්දයට වඩා ටිකක් වැඩියෙන් ඇසේ.

b කථාකරන තරම් ශබ්දයකින් ඇසේ.

C කථාකරන ශබ්දයට වඩා ටිකක් වැඩියෙන් ඇසේ.

d ලඟ තිබෙන කාමරයට ඇසෙන තරම් ශබ්දය වැඩියි.

3. දින කියක් ඔබ නින්දේදි ගොරවයිද?

a හැමදාම

b සතියට දින 3ක් හෝ 4ක්

C සතියට දින 1ක් හෝ 2ක්

d මසකට දින 1ක් හෝ 2ක්

e කිසිම දිනෙක නැත හෝ ඉතා කලාතුරකින්

4. ඔබේ නින්දේදි ගෙරවීම කවදා හෝ අනෙක් අයට කරදරයක් වී තිබේද?

a ඔව් b නැත c නොදනී

5. නින්දේදි ඔබේ හුස්ම ගැනීම නතර වූ බව කිසිවෙකු දැක තිබේද?

a ඔව් b නැත c නොදනී

පිළිතුර “ඔව්” නම්, දින කියක් නින්දේදි ඔබේ හුස්ම ගැනීම නතර වූ බව කිසිවෙකු දැක තිබේද?

a හැමදාම

b සතියට දින 3ක් හෝ 4ක්

C සතියට දින 1ක් හෝ 2ක්

d මසකට දින 1ක් හෝ 2ක්

e කිසිම දිනෙක නැත හෝ ඉතා කලාතුරකින්

6. ඔබට නින්දට පසු විඩාපත් බව හෝ මහන්සිය දැනේද?

a ඔව් b නැත

පිළිතුර “ඔව්” නම්, දින කියක් නින්දකට පසු ඔබට විඩාපත් බව හෝ මහන්සිය දැනේද?

a හැමදාම

b සතියට දින 3ක් හෝ 4ක්

C සතියට දින 1ක් හෝ 2ක්

d මසකට දින 1ක් හෝ 2ක්

e කිසිම දිනෙක නැත හෝ ඉතා කලාතුරකින්

7. අවදියෙන් සිටින අවස්ථාවල ඔබට විඩාපත් බව හෝ මහන්සිය දැනේද?

a ඔව් b නැත

පිළිතුර "ඔව්" නම්, දින කියක් අවදියෙන් සිටින අවස්ථාවල සාමාන්‍ය ප්‍රමාණයට වඩා ඔබට විඩාපත් බව හෝ මහන්සිය දැනේද?

a හැමදාම

b සතියට දින 3ක් හෝ 4ක්

C සතියට දින 1ක් හෝ 2ක්

d මසකට දින 1ක් හෝ 2ක්

e කිසිම දිනෙක නැත හෝ ඉතා කලාතුරකින්

8.1 ඔබ කවදා හෝ පෝළිමක බලා සිටින විටදි නින්දට වැටී තිබේ ද?

a. ඔව් b. නැත

පිළිතුර "ඔව්" නම්, කොපමණ වතාවක් සිදු වුනිද?

a. ආසන්න වශයෙන් සියළුම අවස්ථාවලදි

b. අවස්ථාවන් 3ක් හෝ 4ක්

c. අවස්ථාවන් 1ක් හෝ 2ක්

d. කිසිම දිනෙක නැත හෝ ඉතා කලාතුරකින්

8.2 ඔබ කවදා හෝ දහවල් කාලයේ නිවසේ රූපවාහිනිය නරඹන අතරතුරේදි නින්දට වැටී තිබේ ද?

a. ඔව් b. නැත

පිළිතුර "ඔව්" නම් දින කියක් මෙය සිදුව දැනිද?

a හැමදාම

b සතියට දින 3ක් හෝ 4ක්

C සතියට දින 1ක් හෝ 2ක්

d මසකට දින 1ක් හෝ 2ක්

e කිසිම දිනෙක නැත හෝ ඉතා කලාතුරකින්

9. ඔබට අධිරුධිර පීඩනය තිබේද?

a ඔව් b නැත c නොදනී

Sinhala translated STOP-Bang questionnaire (BOX S2)

ස්ටොප්බැන්ග් ප්‍රශ්නාවලිය

වයස : ..... ස්ත්‍රී : .....

(උසට සාපේක්ෂව බර)-..... බෙල්ලේ වට ප්‍රමාණය:

සෙන්ටිමීටර්.....

01 නින්දේදී ගෙරවීම

තදින්ම නින්දේදී ගොරවයි ද? (කථාකරන ශබ්දයට වඩා හෝ වැඩූ දොරකින් ඇසීමට තරම්)

ඔව් ☐

නැත ☐

02 මහන්සි ද ?

ඔබට නිතර විඩාව/නිදිබර ස්වභාවය දහවල් කාලයේදී දැනේද?

ඔව් ☐

නැත ☐

03 නිරීක්ෂණය

නින්දේදී ඔබේ හුස්ම ගැනීම නතර වූ බව කිසිවෙකු හෝ නිරීක්ෂණය කර තිබේද ?

ඔව් ☐

නැත ☐

04 රුධිර පීඩනය

අධිරුධිර පීඩනයට ප්‍රතිකාර කරනු ලැබ තිබේද?

ඔව් ☐

නැත ☐

05 උසට සරිලන බර ප්‍රමාණය

ඔබේ උසට සරිලන බර ප්‍රමාණය 35 ට වඩාවැඩිය.

ඔව් ☐

නැත ☐

06 ඔබේ වයස

ඔබේ වයස අවුරුදු 50ට වඩා වැඩිය.

ඔව් ☐

නැත ☐

07 බෙල්ලේ වට ප්‍රමාණය

බෙල්ලේ වට ප්‍රමාණය සෙන්ටිමීටර (40cm ට) වඩා වැඩිය.

ඔව් ☐

නැත ☐

Delphi procedure of validating Berlin-S and STOP-Bang-S- Box S3

Step	Procedure
Delphi Round 1	A review form for the study instruments (Berlin-S and STOP-Bang-S) which were prepared after reviewing literature was handed over to the experts included in the Delphi procedure. Review form with a five-point Likert scale (1= Not Appropriate at all, 2= Less Appropriate, 3= Neutral, 4=Appropriate, 5= Highly Appropriate), based on the items comprising each study instruments were used for evaluation in this round focused on the coherence and clarity of the information in the study instruments. Experts were requested to rate each item included in the instrument under the following components. • appropriateness of content • Sinhala translation denotes the meaning in the English version • culturally appropriateness After conducting an extensive analysis of review forms, at the end of the first round disagreements/agreements were recognized.
Delphi Round 2	The PI modified the instruments according to the comments received. These rounds provided experts an opportunity to make further clarifications of both the modified versions and the original versions of both tools.
Delphi Round 3	Study instruments were finally evaluated after making all modifications according to the comments/suggestions received. The feedback of experts was evaluated as the items received consensus and the items not received consensus. The ratings received for each item by experts were recognized and distributed among the group as a summary with modifications done in the instruments. This round provided a final opportunity for participants to modify the instrument. After conducting extensive discussions with the experts involved in the modification process, the final version of Berlin and STOP-Bang-S were granted a 100% acceptance rate.

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