

Validation of the modified Berlin questionnaire to identify patients at risk for the obstructive sleep apnoea syndrome

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Background & objectives: Awareness regarding obstructive sleep apnoea (OSA) among general public as well as practicing physicians is low in India. The present study was undertaken to test the utility of modified Berlin questionnaire for risk categorization of OSA in Indian setting.

Methods: The modified Berlin questionnaire was administered in 180 middle aged adults (of 320 screened), of whom, 104 underwent overnight polysomnography, in a cross-sectional study at a tertiary care, referral center in north India. Questionnaire addressed the presence of frequency of snoring, wake time sleepiness, fatigue, obesity and hypertension. Subjects with persistent and frequent symptoms in any two of these three domains were considered in high risk category for obstructive sleep apnoea. Overnight polysomnography was performed to measure apnoea and hypopnoea index (AHI).

Results: Questions about the symptoms demonstrated internal consistency (Cronbach α correlations 0.92-0.96). Of the 180 respondents to the screening questions, 80 were in the high risk and the rest were in low risk group. For 104 subjects who underwent polysomnography, risk grouping was useful in prediction of AHI. High risk category predicted an AHI >5 with a sensitivity of 86 per cent, specificity of 95 per cent, positive and negative predictive values of 96 and 82 per cent respectively. These results were comparable to Berlin questionnaire study done in the western population for validation.

Interpretation & conclusion: On the basis of the findings of present study it is concluded that administration of modified Berlin questionnaire prior to a polysomnography study can identify high risk subjects and can thus avoid unnecessary polysomnography studies especially in resource-limited settings. To identify subjects at risk for OSA syndrome in general population, this questionnaire can be applied. However, the findings of the present study need to be confirmed further in a large number of subjects in a community-based setting.

Key words Apnoea-hypopnea index - Berlin questionnaire - obstructive sleep apnoea - obstructive sleep apnoea/hypopnoea syndrome - polysomnography - respiratory disturbance index

Obstructive sleep apnoea/hypopnoea syndrome (OSAHS) and its manifestations have been known for many centuries. It is a potentially disabling condition characterized by excessive daytime sleepiness, disruptive snoring, repeated episodes of upper airway obstruction during sleep and nocturnal hypoxemia. A population-based study¹ of workers in Wisconsin in 1993 found that 2 per cent of women and 4 per cent of men had symptoms of daytime sleepiness with OSA. Prevalence of OSA or OSAHS from Wisconsin sleep cohort study done in USA and studies from other countries was almost similar²⁻⁴. A community-based study in middle-aged subjects from New Delhi has reported prevalence of OSA and OSAHS 13.7 and 3.6 per cent respectively⁵. Recognition of OSA by the community physicians all over the world is, however, low. In the Wisconsin sleep cohort study community physicians diagnosed only 7 per cent of women and 12 per cent of men with moderate to severe illness to have OSA. Two studies observed that specialist intervention with diagnostic equipment⁶ or intensive physician education on taking sleep history⁷ improved recognition of OSA among primary care physicians. However, both approaches required substantial professional and technical resources.

Overnight polysomnography (PSG) is considered to be the gold standard for diagnosis of OSA, however, prohibitive cost of the test and long waiting lists limit its widespread access. Although symptom questionnaires have been developed to predict presence of OSA, their overall reliability and utility have not been established.

The Berlin questionnaire⁸ is an instrument validated to use in the western population to determine the occurrence of risk factors for OSAHS namely snoring behaviour, wake-time sleepiness or fatigue and the presence of obesity or hypertension. The questions were selected from literature to elicit factors or behaviours that, consistently predicted the presence of sleep-disordered breathing⁹⁻¹⁴. The questionnaire had symptoms about snoring, excessive daytime sleepiness (EDS), obesity and hypertension.

Questions about these symptoms demonstrated internal consistency (Cronbach α correlations¹⁵, 0.86 to 0.92). The Berlin questionnaire⁸ has been evaluated in the population of Cleveland, Ohio with a sensitivity of 86 per cent and specificity of 77 per cent. No such study has been reported from India. We used the set of screening questions (Annexure I) and validation of the Berlin questionnaire⁸ with certain modifications in Indian setting and named it modified Berlin questionnaire (Annexure II) for risk categorization of OSA.

Material & Methods

Patient selection: The study was conducted at the All India Institute of Medical Sciences (AIIMS) hospital, a tertiary level referral center at New Delhi, India. The study protocol was reviewed and cleared by the departmental research committee and institutional review board of the All India Institute of Medical Sciences. Informed written consent was obtained from all patients. Subjects for the study selected from the patients attending medical outpatient department of AIIMS from April 2000 to April 2002. Subjects of either gender in the age group of 18-60 yr, qualifying the set of screening questions (Annexure I), and residents of New Delhi and nearby areas were considered eligible. Patients with history of alcoholism, chronic anxiolytic/sedative drug use, associated respiratory, renal, hepatic or cardiovascular disease or upper respiratory tract infection within the past one week as well as those who were pregnant or critically ill were excluded.

Subjects who expressed their intention to participate and satisfied above criteria were administered screening questionnaire (Annexure I). Modification in the Berlin questionnaire (Annexure II) included changes in the questions in category 2. As driving is not common in India, we included questions more on wake-time sleepiness such as history of sleepiness while waiting for an appointment with the doctor, while watching television at home, or while waiting in the queue to make payment of telephone or electricity bill.

All subjects were explained about details of the study. A total of 320 consecutive subjects were administered screening questionnaire. Of these, 180 subjects gave at least one positive response to the four screening questions of the questionnaire (Annexure I). All the 180 subjects were requested to fill in the proforma and the modified Berlin questionnaire (Annexure II) themselves, preferably in the presence of subjects' bed partners. Subjects who could not read and write were administered the questionnaire by the first author (SKS) with the help of their bed partners. Locally translated version (Hindi) of questionnaire was used for subjects who could not read and write English. The Hindi questionnaire was back translated into English with no difference in the meaning conveyed.

Risk categorization: Subjects were divided into high risk and low risk categories on the basis of modified Berlin questionnaire and risk categorization as described under Berlin study results⁸. A 4-point frequency scale [0- never, 1- rarely (1-2/month), 2-sometimes (1-2/wk), 3-frequently (3-4/wk), 4-always (>4/wk)] was used for defining various indices like snoring, choking, caffeine and alcohol index. Subjects smoking was given score according to the following criteria: 0- never, 1- (1-2 cigarettes or beedies/day), 2- (3-5 cigarettes or beedies/day), 3- (5-10 cigarettes or beedies/day), 4- (> 10 cigarettes or beedies/day). Pre-determination of high risk and lower risk for sleep apnoea or syndrome was based on responses in three symptom categories. In category 1, high risk was defined as persistent symptoms (>3 to 4 times/wk) in two or more questions about their snoring. In category 2, high risk was defined as persistent symptoms (>3 to 4 times/wk) in two or more questions about their wake time sleepiness. In category 3, high risk was defined as a history of high blood pressure as per the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI)¹⁶ or a body mass index (BMI)¹⁷ >25 kg/m². To be considered high risk for obstructive sleep apnoea syndrome, patients had to qualify as high risk for at least two symptom categories. Those who denied having persistent

symptoms or who qualified for only one symptom category were placed in the low risk group. Eighty subjects were in high risk and 100 were in low risk category.

A detailed physical examination was done in all subjects. Blood pressure was measured with a mercury sphygmomanometer to the nearest 2 mmHg in recumbent position after at least five minutes of rest. Subjects were advised to refrain from smoking or ingesting caffeine for 30 min prior to blood pressure measurement. A variety of large cuff sizes was used wherever necessary to ensure that bladder length was at least 80 per cent of the arm circumference. In case of an abnormal blood pressure recording, another reading was obtained after 5 min of rest. An average of six readings of systolic and diastolic pressure on two occasions was taken for analysis. The mercury sphygmomanometer was periodically validated against a Hawksley Random Zero Sphygmomanometer (Hawksley, Lancing, Sussex, UK). A history of antihypertensive medication intake was also recorded in subjects with hypertension.

Hypertension was classified as per the JNC VI¹⁶: the optimal BP (systolic pressure of <120 mm Hg and diastolic pressure of <80 mm Hg), normal (systolic pressure of 120 to 129 mm Hg or diastolic pressure of 80 to 84 mm Hg), or high normal (systolic pressure of 130 to 139 mm Hg or diastolic pressure of 85 to 89 mm Hg). If the systolic and diastolic blood pressure readings belonged to different categories, then higher of the two readings was used to assign the blood-pressure category.

A specialist otorhinolaryngologist, blinded to PSG findings, carried out examination of upper airway in all subjects included in the study. A specific note of the following abnormalities was made: macroglossia, pharyngeal crowding, bulky uvula, retrognathia, tonsillar enlargement and deviated nasal septum.

All subjects underwent complete blood count (CBC), liver and renal function tests, lipid profile,

chest radiograph, 12-electrocardiogram and lung function testing. The following spirometry variables were also analyzed; Forced vital capacity (FVC), forced expired volume in one second (FEV_1), peak expiratory flow rate (PEFR) and ratio of forced expired volume in one second and forced vital capacity (FEV_1/FVC). Lung volumes and their subdivisions were measured by using a constant volume variable pressure body plethysmograph (P.K. Morgan Chatham, Kent, UK).

Anthropometric profile: Body weight was recorded (to nearest 0.5 kg) in all patients, in erect position without shoes and wearing only light indoor clothes, with an electronic scale (Tanita body composition analyzer-TBF 300 G.S., Japan). Height was measured to the nearest 1 cm and body mass index (BMI) was calculated as body weight/height² (kg/m²). Neck circumference (NC) was measured at the level of cricothyroid membrane using a non-elastic measuring tape. Neck length (NL) was measured from occipital tubercle to the vertebra prominens. A height-corrected measure for NC, percentage predicted neck circumference (PPNC) was computed using the formula, $PPNC = (1000 \times NC) / (0.55 H + 310)$. Waist circumference was measured midway between the lower rib cage margin and the anterior superior iliac spine. Hip circumference was measured at the maximum circumference of the buttocks, the subject standing with feet placed together and waist-hip ratio (W-HR) was calculated.

Skinfold thickness was measured using Lange skinfold calipers (Beta Technology Inc., Santa Cruz, CA, USA) to the nearest 1 mm. Mid arm circumference (cm) was measured at the level of mid arm taking acromion process and olecranon as reference points. Triceps and biceps skinfold thicknesses were measured midway between the acromion process of scapula and the olecranon process. Subscapular skinfold thickness (SSFT) was measured at the inferior angle of scapula in mid-axillary line and suprailiac skinfold thickness measured just above the highest point of iliac crest. All measurements were done in triplicate and the mean was recorded.

Sleep studies: Of the 180 subjects, 104 underwent polysomnography as described previously¹⁸. All subjects underwent sleep study within one month of completing the questionnaire. Subjects were asked not to sleep in the afternoon on the day of study and not to take alcohol anxiolytic/sedative drugs. The subject was hooked to Alice 3 infant and adult computerized polysomnography machine (Healthdyne Technologies, USA) by standard gold cups after cleansing the area of attachment by spirit followed by Omni prep[®]. The subject was requested to sleep at around 21:00 h. The recording of sleep study started after ensuring that the impedance of recording electrodes was set to zero. Various parameters monitored included electroencephalogram (EEG), electro-oculogram (EOG), electrocardiogram (ECG), chin and leg electromyogram (EMG), nasal airflow, tracheal breath sounds, thoracic wall and abdominal movements, transcutaneous oxygen saturation, body position and continuous positive airway pressure (CPAP) titration, where required. All subjects underwent polysomnography for at least 6 h. The sleep data recorded by the computer were manually scored for sleep stages, apnoeas, and hypopnoeas. The apnoea was defined as cessation of oro-nasal airflow for >10 sec. Obstructive apnoeas were scored when airflow was absent but respiratory efforts were present. Hypopnoea was defined as a discernible reduction in respiratory airflow during a preceding period of normal breathing for >10 sec accompanied by a decrease of 4 per cent or more in oxyhaemoglobin saturation during sleep. Apnoea-hypopnoea index (AHI) was calculated based on the following formula: $AHI = (\text{total no. of obstructive apnoeas} + \text{total no. of hypopnoeas}) / \text{total sleep time in hours}$.

Statistical analysis: Data were recorded on a pre-designed data sheet and managed on an 'Excel' spreadsheet. All entries were double checked for any possible feeding error. Cronbach α value¹⁵ was used for assessment of internal reliability between responses to various questions or items in each category. Coefficients above 0.7 are generally regarded as acceptable, 0.8 and above are good and 0.9 and above are considered excellent.

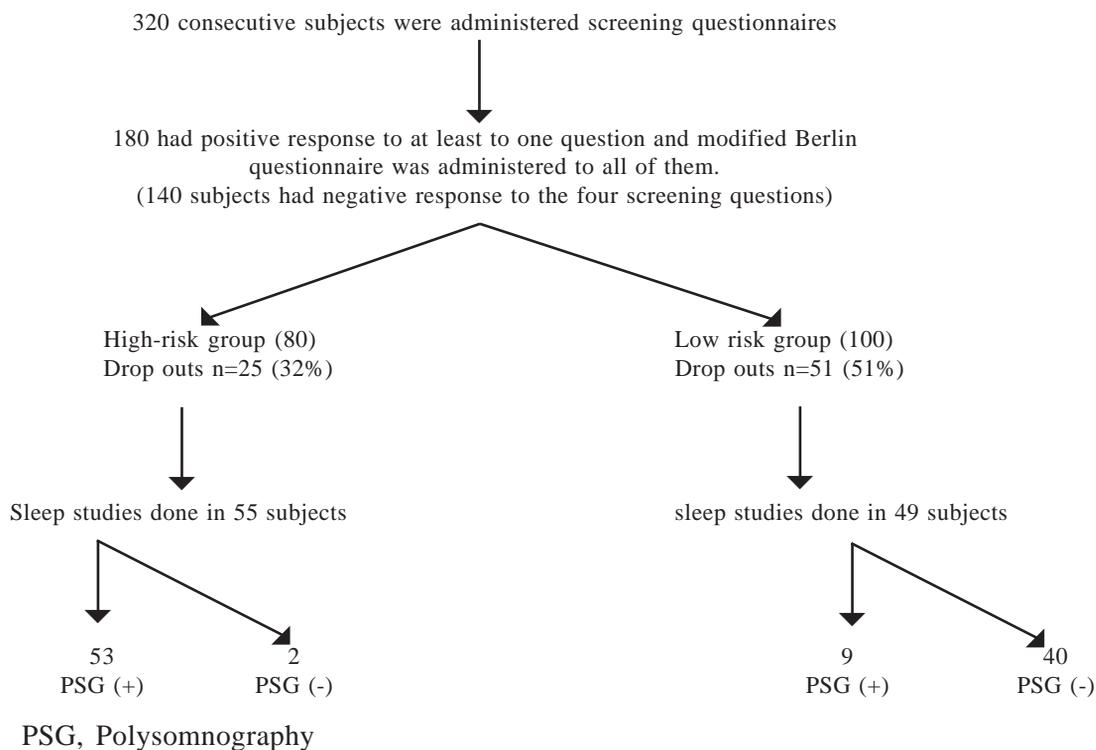


Fig. 1. Administration of screening and modified Berlin questionnaires, risk grouping and results of study.

Table I. Demography and anthropometric characteristics in cases and controls

Variable	Cases (n=62)	Controls (n=42)
Age (yr)	43 ± 9**	36 ± 9
Neck circumference (cm)	40.3 ± 3.1**	35.6 ± 3.4
Neck length (cm)	10.7 ± 2.3	10.5 ± 2.4
PPNC (%)	100 ± 7.6**	89.2 ± 7.6
Body mass index (kg/m ²)	30.9 ± 7.3**	24.2 ± 5.2
Waist hip ratio	1 ± 0.7**	0.9 ± 0.2
Mid arm circumference (cm)	33.5 ± 3.7**	28.9 ± 4.1
SSFT* (cm)	25.3 ± 9.9*	19.2 ± 9.2

SSFT* recorded in 45 cases and 42 controls. All data are presented as mean (SD). PPNC = [(1000×NC)/(0.55 × H+310)]. PPNC, percentages of predicted neck circumference for height; SSFT, sub-scapular skin fold thickness
*P**<0.05, **<0.001 compared to controls
 Values are shown as mean ± SD

Anthropometric measurements and PSG findings in cases and controls were compared using Student's t-test. Chi-square test was used to study the association between the outcome variable (AHI) and various ordinal variables. Variables showing statistically significant association at *P*<0.05 in univariate analysis were considered as candidate predictors to be used in multivariate analysis. Step-wise multiple logistic regression analysis was used to identify significant independent predictors for OSA. Statistical analysis was performed using statistical software package 'STATA version 10.0' [(intercooled version), Stata Corporation, Houston, Texas, USA].

Results

Anthropometry and demography profile of cases and controls: Subjects with polysomnographic evidence of AHI >5/h were categorized as cases (n=62) and the subjects with AHI <5/h as controls (n=42) (Fig. 1).

Majority of the subjects were males (80%). Cases had significantly higher neck circumference and were older than controls. Statistically significant difference was observed between percentages of predicted neck circumference for height (PPNC) of cases and controls ($P<0.001$). Neck length was not significantly different between cases and control groups. BMI ranged from 14.9 - 58.3. Seventy three per cent subjects had BMI >25 but only 50 per cent patients felt they were actually obese. The difference in BMI between cases and controls was statistically significant ($P<0.001$) (Table I). Fifty six per cent of the subjects were hypertensive. Only 40 per cent of these subjects had their hypertension diagnosed before they were included in the study. Remaining 16 per cent were detected as hypertensive during this study.

The difference in WHR, mid-arm circumference and SSFT between cases and controls was statistically significant ($P<0.001$, 0.05).

Pulmonary function testing and upper airway (nasal and pharyngeal) examination: Pulmonary function testing results were available in 70 subjects. No significant difference in FEV₁, FEV₁ / FVC, PEFR and FVC was found between cases and controls. Nasal and throat abnormalities were detected in 18 subjects and 86 subjects did not have any abnormality. Seventeen (94%) subjects were cases among the group of 18 subjects who had upper airway abnormalities. The abnormalities included enlarged tonsils, abnormal pharyngeal anatomy, nasal obstruction due to deviated nasal septum and nasal polyps.

Polysomnography results: Total duration of sleep differed in both cases and control groups and was statistically significant ($P<0.05$). Rapid eye movement (REM) sleep between the groups was not significantly different. Lowest baseline SpO₂ was 84 per cent and it was significantly lower ($P<0.05$) in cases than in controls (Table II).

Validation of modified Berlin questionnaire: The total number of patients in the present study was the same as in the original study on the Berlin questionnaire⁸. The high risk group subjects were low in number. Specificity, positive predictive value and negative predictive value were significantly higher than in the earlier study on the Berlin questionnaire⁸. Combined misclassification rate in the present study was lower in the control group (5 vs 24%) as compared to the earlier study on the Berlin

Table II. Sleep study characteristics in cases and controls

Variable	Cases (n=62)	Controls (n=42)
Total sleep time (min)	425.5 ± 77*	382.5 ± 6.4
Rapid eye movement sleep (%)	47.6 ± 40.9	41.3 ± 3.4
Obstructive apnoeas (n)	104.9 ± 106**	1.6 ± 0.8
Baseline SpO ₂ (%)	94.4 ± 2.8*	95.9 ± 1.9
Minimum saturation during sleep (%)	62 ± 21*	75 ± 20

All data are shown as mean ± SD

SpO₂, arterial oxygen saturation as measured by pulse oximetry during sleep

$P^*<0.05$, $^{**}<0.001$ compared to controls

Table III. Comparison of high risk and low risk groups using apnoea/hypopnoea index (AHI) ≥ 5 as cut-off

PSG	High risk	Low risk	Total
Cases (AHI >5)	53 (61*)	9 (6*)	62 (69*)
Controls (AHI <5)	2 (8*)	40 (25*)	42 (33*)
Total	55 (69*)	49 (31*)	104 (104*)

All data are shown in numbers. Definitions of high risk, low-risks are provided in Material and Methods. *Numbers in parentheses are results of Berlin study⁸

Sensitivity	86% (88*)
Specificity	95% (76*)
Positive predictive value	96% (88*)
Negative predictive value	82% (81*)
Misclassification rate in cases	14.5% (9*)
Misclassification rate in controls	5% (24*)

*Numbers in parentheses refer to numbers in the Berlin study

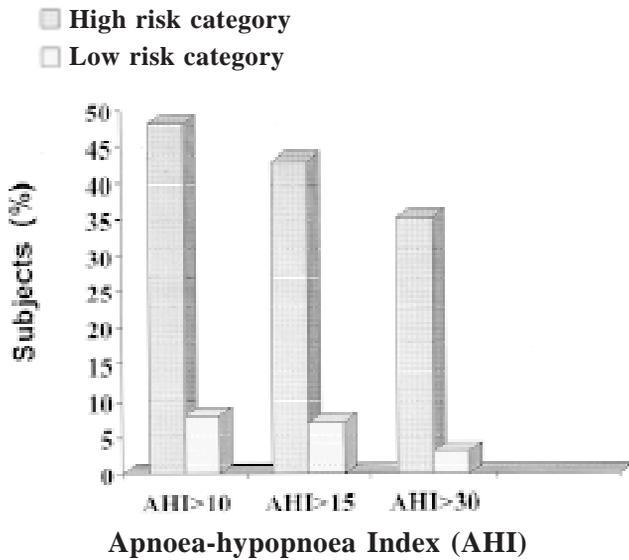


Fig. 2. The distribution of AHI in the high risk and low risk groups.

questionnaire. Misclassification rate was 19.3 per cent in both cases and controls (Table III).

Distribution of AHI in the high and low risk groups:

A total of 48 subjects in the high risk group and 8 in the low risk group had AHI >10, 43 subjects in the high risk group and 7 in low risk group had AHI >15, whereas 35 subjects in the high risk group and 3 subjects in low risk group had AHI >30 (Fig. 2).

Discussion

A number of epidemiological studies have been performed all over the world in various ethnic and racial groups to determine the prevalence of OSA and OSAHS. Unfortunately data related to sleep breathing disorders among Indians are sparse. It is a prerequisite to have a symptoms questionnaire to screen the patients at risk for OSAHS before a polysomnography is done, due to its high cost and non-availability at all centers in developing countries like India where resources are limited. Having a symptom-based questionnaire with good predictive ability will avoid unnecessary sleep studies in the subjects who are not at high risk for having OSA.

Therefore, a modified symptom-based questionnaire was used to identify the patients at risk for OSA in the Indian population. The modification was done to suit questions to our population. The drop out rates of 32 and 51 per cent in high and low risk groups respectively were high since the subjects were attending the hospital for non-sleep related problems. Discrepancy in drop out rates was expected since high risk group subjects with significant complaints, might have become aware about the possible presence of sleep apnoea in them. In the present study no data were missing as it had happened in a few questionnaire based studies¹³ in the past. This could be attributed to the simple questions in the questionnaire and filling by the subjects in the presence of a qualified medical practitioner. Internal reliability between responses to each category of questions calculated by using Cronbach α correlations¹⁵ showed values in good reliability range. Based on responses to questionnaire, we calculated snoring, choking, alcohol, smoking indices of which choking and snoring indices were found to be independent predictors of mild to moderate OSA (AHI \geq 5-15/h) and moderate to severe OSA (AHI \geq 30/h) respectively.

We used gold standard diagnostic study¹⁹ (overnight polysomnography) for our study population. According to American²⁰ and Australasian guidelines²¹ also overnight polysomnography is considered to be the gold standard for diagnosis of OSA. International task force²² on standardization of definition of sleep-disordered breathing recommends AHI >15 per h as cut-off. The definition of OSA is arbitrary, and it has been suggested that an AHI >5/h is a low cut-off value, especially for older people^{23,24} and many studies have used higher cut-off values of AHI. AHI >5 per h was used as cut-off for defining OSA, since our study was performed to validate the questionnaire in subjects at risk for OSA and not to identify the patients with moderate and severe OSA.

Annexure-I*Screening questions:*

1. Do you snore?
2. Do you feel tired after waking up from sleep?
3. Do you feel you are obese?
4. Are you a hypertensive?

3-4 times a wk
 1-2 times a wk
 1-2 times a month
 Never or nearly never

Category 2:

1. How often do you feel tired or fatigued after your sleep?

Nearly every day
 3-4 times a wk
 1-2 times a wk
 1-2 times a month
 Never or nearly never

Annexure-II

Modified Berlin questionnaire (used at AIIMS, New Delhi)

Category 1:

1. Do you snore?

Yes
 No
 Don't know

2. Your snoring is

Slightly louder than breathing
 As loud as talking
 Louder than talking
 Very loud can be heard in adjacent rooms

3. How often do you snore?

Nearly every day
 3-4 times a wk
 1-2 times a wk
 1-2 times a month
 Never or nearly never

4. Has your snoring ever bothered other people?

Yes
 No

5. Has anyone noticed that you quit breathing during your sleep?
 If yes, how frequently?

Nearly every day
 3-4 times a wk
 1-2 times a wk
 1-2 times a month
 Never or nearly never

6. Do you choke while you are sleeping? If yes, how frequently?

Nearly every day

Nearly every day
 3-4 times a wk
 1-2 times a wk
 1-2 times a month
 Never or nearly never

2. During your wake time do you feel tired, fatigued or not up to at par? If yes, how frequently?

Nearly in all visits
 In 1-2 visits
 In 3-4 visits
 Never or nearly never

3. Have you ever fallen asleep while waiting in a line to meet your doctor? If yes, how frequently?

4. Have you ever fallen asleep while watching television at your home during daytime? If yes, how frequently?

Nearly every day
 3-4 times a wk
 1-2 times a wk
 1-2 times a month
 Never or nearly never

5. Have you ever fallen asleep while waiting in a line to pay your electricity and telephone bills? If yes, how frequently?

Nearly every visit
 In 3-4 visits
 In 1-2 visits
 Never or nearly never

Category 3:

- Do you have high blood pressure?

Yes
 No
 Don't know

The BMI >25 kg/m² was used as cut-off for obesity¹⁷. The mean BMI was significantly higher in cases than the controls. Both BMI and hypertension appeared to be associated with habitual snoring and OSA. A similar association was found in the Berlin questionnaire⁸. The predictive value of this combination of symptoms was high. Various studies have reported frequency of hypertension 40-80 per cent²⁵ in OSA. In the present study the frequency of hypertension among cases was 53 per cent. The JNC VI classification¹⁶ was used as JNC VII classification was not available when this study was started. These results are in accordance with results of other studies²⁵.

To conclude, the modified Berlin questionnaire evaluated in Indians was found to be valid and applicable due to the following reasons: (i) The internal reliability was good among the responses to questions asked in each category. (ii) Risk categorization done on the basis of the modified Berlin questionnaire emerged as a good independent predictor for the presence of both mild and moderate OSA. Further validation of the modified Berlin questionnaire need to be done in large samples in different parts of the country.

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