

Obstructive Sleep Apnea in a rural population in South India: Feasibility of health care workers to administer level III sleep study

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ABSTRACT

Objectives: To estimate the occurrence of obstructive sleep apnea (OSA) and its risk factors in a rural Indian population using screening questionnaire and Level III sleep study. To determine the feasibility to train community health workers to administer Level III sleep study in the high-risk population. **Materials and Methods:** The study was conducted from seven villages with adult population of 2247, in Mugalur, near Bengaluru, from January to April 2014. Berlin questionnaire was used to screen 321 participants chosen by stratified random sampling. A total of 26 out of 321 patients underwent Level III sleep study at home, administered by the health workers, who were trained in three sessions to hook up the machine. Data were verified by a certified sleep physician. **Results:** The mean age was 39.43 ± 15.6 years with the M:F ratio of 0.98:1. Prevalence of risk of OSA by Berlin questionnaire was 8.72% (95% confidence interval [CI] 5.63, 11.81) in the total population, 7.4% in males and 11.7% in females. Older age (odds ratio [OR] 3.97; CI 1.63, 9.6), hypertension (OR 11; CI 4.3, 28.2), obesity (OR 2.35; CI 1, 5.5), and higher Mallampati score (OR 3.78; CI 1.7, 8.4) were significantly associated with high risk of OSA ($P = 0.0001-0.04$). Twenty-six patients underwent Level III sleep study and OSA was diagnosed in 12 patients. The mean apnea-hypopnea index (AHI) of this group was 9.7/h. The prevalence of OSA by AHI criteria was 3.74%. **Conclusions:** OSA is underdiagnosed in rural populations, although risk factors are present. Training community health workers to administer Level III sleep study is a feasible and cost-effective strategy.

KEY WORDS: Berlin questionnaire, community health workers, obstructive sleep apnea, rural

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INTRODUCTION

The abnormal collapse of the pharyngeal airway during sleep leading to apneic episodes and the resulting repetitive arousals is termed as obstructive sleep apnea (OSA).^[1] OSA is associated with worsening hypertension, arrhythmias, stroke, and myocardial infarction.^[2-4]

Various global epidemiologic studies have demonstrated the prevalence of OSA to vary widely from 6.5% and 9% in women and between 17% and 31% in men.^[1,5] However,

more recent literature quotes the prevalence of OSA between the age group of 30 and 70 years as around 34% and 17% in men and women, respectively.^[6]

Young *et al.* estimated that among middle-aged adults, 1 in 20 has clinically undiagnosed OSA.^[1] Mirrakhimov *et al.* have concluded from a systematic review of 47,957 participants, that there is a paucity of prevalence studies from Asia.^[7]

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In India, Udawadia *et al.* have estimated the prevalence of OSA in urban Indian population as 7.5%,^[8] whereas increased prevalence of 13.5% was noted by Sharma *et al.*^[9]

Approximately 70% of India's 1.2 billion population reside in rural areas, but greater connectivity and advances in infrastructure and technology have made the rural population to adopt an increasingly urban lifestyle. This has translated to progressively increasing the prevalence of smoking and noncommunicable diseases such as cardiovascular diseases^[10,11] which are strongly associated with OSA. Snoring and sleep during daytime are culturally acceptable in India; hence many people suffering from OSA remain undiagnosed.^[8] Undiagnosed OSA is a major noncommunicable public health risk.

There are no studies of OSA and potential risk factors associated with OSA in the rural population in India. OSA is a treatable disease. Early identification and treatment would help to prevent morbidity and complications due to OSA.

This study aims to address this deficiency and to add strength to the evidence that OSA is probably as prevalent in the rural population as in the urban areas.

MATERIALS AND METHODS

Primary objective

(1) To estimate the occurrence of OSA in a rural setting using a stepwise model of screening questionnaire and Level III sleep study and (2) To assess the feasibility to train community health workers to conduct a Level III sleep study.

Secondary objective

The secondary objective was to describe the risk factors associated with OSA in a rural population.

Participants and method

A stratified random sample from a rural population of 2247 adults in 7 villages, located in Mugalur, 56 km from Bengaluru, were interviewed using a standardized questionnaire (modified Berlin questionnaire [validated in Indian population] and Epworth Sleepiness Score [ESS]). Mugalur and the near-by villages were chosen as the study site, as our institution has an outreach primary medical center in Mugalur. The study was initiated after obtaining approval from St. John's Medical College Ethics Review Board.

The information of total adult population in the seven villages was taken from the national census data and every seventh individual on the list was approached for inclusion in the study [Figure 1]. It was predetermined that the next person on the list would be approached if a subject did not consent for the study. However, none of the participants denied consent. A predefined pro forma was used to accrue

data after obtaining written informed consent from the patient. Author (AMP) visited the rural area during weekends and college holidays to collect data by a house-to-house survey, visiting the preselected participant at their home.

Inclusion criteria: All the participants above 18 years of age were included. Exclusion criteria: Since this was a prevalence study, no participant was excluded.

Data regarding the demographics, smoking history, alcohol use, and comorbid illness were collected. Socioeconomic status was assessed by modified Kuppuswamy scale.^[12] Data regarding sleep were obtained using modified Berlin questionnaire (validated in Indian population)^[13] and ESS.

Participants categorized as high risk for OSA (two or more checked categories in Berlin questionnaire) were subjected to a Level III sleep study (Resmed Apnea-link plus™) in the comfort of their home. This device uses noninvasive flow monitoring, pulse oximetry, and thoracic and abdominal bands to define airflow obstruction by the absence of flow despite continuing ventilatory effort; it is widely used as a screening test for OSA before polysomnography referral and has a sensitivity of at least 85% for any OSA and near 100% for moderate-to-severe OSA.^[14-16] The community health workers (four workers) in the primary health center in Mugalur were trained, in three 1 h sessions, about the sleep disorder, communication skills, and to hook-up the Level III sleep screener in the study participants. The community health worker visited the participants' home and connected the sleep screener at night. They collected the sleep screener on the next day morning. The sleep studies were retrieved and stored in the primary health center's computer and later transported to our center for analysis and interpretation. The sleep screening studies were scored by two trained technicians and verified by a certified sleep specialist (UD). Participants positive for OSA (apnea-hypopnea index [AHI] ≥ 5) were offered further management.

Outcome measures

The presence of OSA was defined by an AHI of $\geq 5/h$ on the sleep study. Apnea was defined as per AASM scoring manual (version 2.0.2)^[17] (There is a drop in the peak signal excursion by $\geq 90\%$ of preevent baseline using an oronasal thermal sensor and signal drop lasts for ≥ 10 s). Hypopnea is defined when the peak signal excursions drop by $\geq 30\%$ of preevent baseline and the duration of signal drop is ≥ 10 s along with $\geq 3\%$ oxygen desaturation from preevent baseline. Oxygen desaturation index was defined as average number of desaturation $\geq 4\%/h$.

Sample size

To estimate OSA prevalence of 6%, with a power of 80% and an alpha error of 5%, the calculated sample size was 268 participants.

Statistics

The descriptive data were expressed as mean, median, standard deviation, and range. Multivariate binary

logistic regression was used to analyze the effect of risk factors on the prevalence of OSA. Chi-square test and Mann–Whitney U-test were used to compare risk factors between the participants who were positive and negative for OSA. $P < 0.05$ was considered statistically significant. Data collected were analyzed with SPSS version 17 (SPSS Inc, Chicago, IL, USA).

RESULTS

The total adult population in 7 villages in rural Mugalur was 2247. Three hundred and twenty-one participants were selected from the census data, by stratified random sampling with a sampling interval of 7. The mean age of the population was 39.43 ± 15.6 years (range- 18–90 years) with the male: female ratio of 0.98:1. The mean BMI in the high-risk category by Berlin questionnaire (27.9 kg/m^2) was significantly higher than that seen in the low-risk category (23.7 kg/m^2)

The prevalence of risk of OSA by Berlin questionnaire was 8.72% (95% confidence interval [CI] 5.63, 11.81) in the total study population, 7.4% in males and 11.7% in females [Table 1]. The risk for OSA was higher in females, but it was not statistically significant. The factors such as older age (OR-3.97; CI 1.63, 9.6), hypertension (odds ratio [OR]-11; CI 4.3, 28.2), obesity (OR-2.35; CI 1, 5.5), and higher Mallampati score (OR-3.78; CI 1.7, 8.4) were significantly associated with high risk of OSA [Table 1]. Conversely, the other parameters such as socioeconomic status, smoking, alcohol use, diabetes mellitus, and neck circumference measured were similar in both risk groups.

Among the 321 participants, 28 participants were in the high-risk category by Berlin questionnaire, of whom 26 underwent the Level III sleep study, as two participants withdrew consent. Four studies were technically unsatisfactory (for reasons such as flow sensors were disconnected, recording available for 2–3 h only). OSA was diagnosed in 12 participants, of whom 7 were male. The mean AHI of this group was 9.7/h. One outlier had an AHI of 53.2/h, hence was not included in statistical analysis to estimate the mean AHI. The prevalence of OSA by AHI criteria was 3.73%.

DISCUSSION

India is the second most populous country in the world with a total population of 1210.1 million and 833.1 million (68.84%) of them reside in rural areas as per national census data in 2011.^[18] The growth rate of the rural population is 31.8% as against 12.18% in the urban population.

Swaminathan *et al.* have exposed that more than 50% of the rural population had a metabolic disorder (diabetes/prediabetes), about 40% had suboptimally controlled hypertension and one-third population had dyslipidemia.^[19] Despite the current prevalence of noncommunicable diseases being lower in the rural population than in urban areas, the burden of disease is huge considering the higher number of people residing in the rural areas.

Despite the fact that noncommunicable diseases such as cardiovascular diseases, diabetes, and hypertension are on the rise in rural population and their implicated risk with OSA, the presence of OSA in rural areas remains unexplored.

OSA has been implicated as a causal factor in atherogenesis leading to stroke and myocardial infarction, secondary to exposure to chronic intermittent hypoxia. OSA has caused arrhythmias and sudden cardiac death.^[20] People suffering from OSA, find difficulty in concentrating and find themselves falling asleep at work, while watching TV or even when driving leading to accidents on the road and at workplace.^[21] Other neurologic complications include memory problems, morning headaches, and depression.^[22] Due to the nonspecific symptoms, a large proportion of OSA is not suspected and are left undiagnosed.

Prevalence of obstructive sleep apnea in rural population

Our study has evinced that the prevalence of risk of OSA is less in rural population (8.7%) when compared to urban population (9.7%–13.5%). This is in contrast to a Turkish study, where rural participants suffered from more snoring and apneas when compared to urban participants (52.6% vs. 46.6%).^[23]

Table 1: Characteristics of high- and low-risk groups by Berlin questionnaire

Characteristics	n (n=321)	High risk (n=28)	Low risk (n=293)	OR	95% CI	P
Age (mean age in years)		48.9	38.5	3.97 [‡]	1.63-9.6	0.0023
Sex (male:female)		11:17	148:145	1.5	0.71-3.4	0.25
Socioeconomic status		3.93	3.65		-0.57-0.02	0.06
Smoking	38	2	36	0.54	0.12-2.4	0.42
Alcohol consumption	16	2	14	1.5	0.33-7.11	0.58
Hypertension	24	10	14	11	4.3-28.2	0.0001
Diabetes	25	4	21	2.15	0.68-6.8	0.18
Obesity (BMI >25)	171	20	151	2.35	1.5-5	0.04
Mallampati score (3 and 4)	101	17	85	3.78	1.7-8.4	0.001
Neck circumference		34.8	33.4	1.4	0.82-9.2	0.08

[‡]OR (for age only) for comparing participants arbitrarily grouped below 40 years and above 40 years of age. OR: Odds ratio, CI: Confidence interval, BMI: Body mass index

The prevalence of confirmed OSA in rural population (3.73%) is comparable to the prevalence of other noncommunicable disease such as diabetes in rural India (3%–8.3%).^[24] This fact highlights that OSA is an important contributor of modifiable noncommunicable disease.

There are many hospital-based and urban area-based studies on OSA reported from India.^[25-29] A systematic literature search did not reveal any prior studies on the prevalence of OSA in rural India. More studies are essential, targeting rural population in various parts of India, to unmask the undiagnosed OSA.

Risk factors for obstructive sleep apnea in rural population

Various studies across the world, done on the prevalence of OSA, have estimated it to be ranging from 4.1%, 6%,^[30,31] to 29.4%^[32] based on questionnaires and 11.4% diagnosed by full polysomnography.^[33]

These studies discuss parameters such as increasing age, male sex, obesity, loud snoring, urban residency, smoking and drinking status, and lower socioeconomic status as risk factors for OSA.

Our study also coincides with the prevalence rate and the risk factors discussed in the other parts of the world, barring a few which are mentioned below.

It is worrisome to note that obesity, one of the important risk factor, is noted to be prevalent in the current study population, with 53.27% (171/321) of them having a BMI ≥ 25 kg/m² (Asian standards).^[34] This evidence shows that obesity is increasing in the rural population. This fact also refutes previous studies, which have noted obesity to be more prevalent in urban population in comparison to rural population, since the majority of the rural people are engaged in physically demanding jobs such as agricultural and labor work.^[35]

In the current study, socioeconomic status could not be assessed as a risk factor as variance among the study participants was minimal. Respiratory diseases and smoking also could not be identified as significant risk factors. This was due to the small number of participants having the said risk factors.

Portable monitoring/diagnostics

Previous clinical trials have shown that home portable monitoring is accurate and feasible for the diagnosis of OSA in a high-risk urban population.^[36] The feasibility of an unattended two channel device to detect OSA was studied in rural Queensland and New South Wales.^[37] The investigators had shown that 93% of the studies were technically adequate. Our study shows a comparable adequacy of 86.4%.

A stepwise model of screening questionnaire followed by home oximetry was proven as an effective approach to identify OSA in a primary care setting.^[38] Our study also

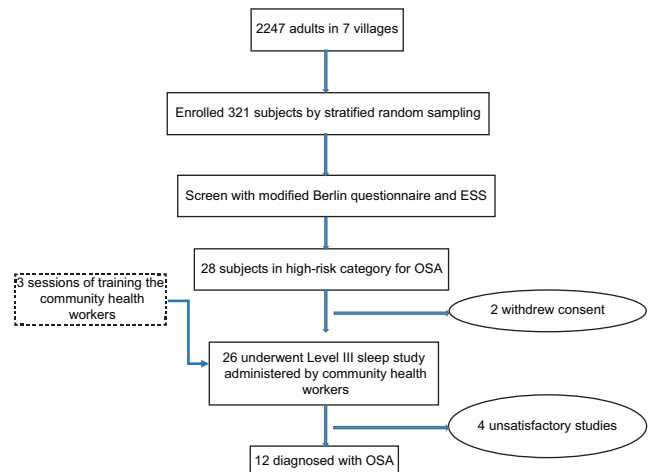


Figure 1: Study protocol

confirms this fact. Rural population have poor access to higher medical centers for sophisticated testing, and hence, the strategy of initial screening, diagnosis, and further referral saves valuable time and resources for the patient and the provider.

Community health worker administered sleep study

There were no previous studies available in literature (PubMed, Scopus), reporting on community health workers administering sleep study. Clinical guidelines recommend that “an experienced sleep technologist must apply the sensors or directly educate patients in sensor application.”^[39] The current study proves the feasibility of training community health workers to successfully hook-up the Level III sleep study device. Three 1 h sessions were adequate to train the community health workers about the need for the study and how to connect the machine. Our study shows a technical adequacy of 86.4%. This provides us with a low-cost and feasible solution involving community health workers, in a rural population in which OSA is largely undiagnosed.

Limitations of the study

A Level I polysomnogram comparison to validate the Level III sleep study in the rural population could not be done due to logistics challenge. A Level I polysomnogram is not accessible to the rural population and our study was designed based on this realistic understanding. A few people who scored as low risk by Berlin questionnaire might have missed the diagnosis of OSA as they were not enrolled into the second phase sleep study.

CONCLUSIONS

The prevalence of OSA by AHI criteria in rural India is 3.73%. When extrapolating this data to the total rural population of India, which is 974.3 million, the prevalence of OSA amounts to 36.34 million individuals. The burden of undiagnosed OSA is huge when considering this rural

population. This condition is underdiagnosed in rural and urban settings, although similar risk factors are present.

Questionnaires are an easy and reliable method to distinguish between high- and low-risk individuals. Older patients with hypertension, obesity, and Mallampati score of 3 or 4 should be evaluated for OSA with a screening questionnaire. In rural populations, there are inadequate facilities for diagnosis of OSA. This can be overcome using a Level III sleep study device as used in this study.

This stratagem of initial screening by questionnaire followed by home-based Level III sleep studies in the high-risk population improves health care by unmasking previously undiagnosed OSA. Trained community health workers can be a worthwhile resource, to resolve the conundrum of undiagnosed OSA.

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Conflicts of interest

There are no conflicts of interest.

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