A STUDY TO ESTIMATE PREVALENCE OF OBSTRUCTIVE SLEEP APNOEA SYNDROME WITH MODIFIED BERLIN QUESTIONNAIRE: AN INDIAN SCENARIO

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ABSTRACT

Introduction: The burden of obstructive sleep apnoea syndrome (OSAS) is rapidly increasing in developing countries like India since the last decade.

Background: To know the prevalence estimates for key symptoms and features that can indicate the presence of OSAS in Indian population.

Material and Methods: A single centre cross-sectional study was conducted from August 2003 to July 2004 on consecutive apparently healthy attendants in age group of 25-64 years coming to outdoor of Department of Pulmonary Medicine, King George Medical University, Lucknow, India. We recorded data on a pre-designed proforma and took interview based on pre-tested Berlin Questionnaire (BQ) with some relevant modifications. Epworth sleepiness scale (ESS) score was also assessed for excessive daytime sleepiness (EDS). We also evaluated for some risk factors like smoking, alcoholism and use of sedative or tranquilizers.

Results: Out of 816 subjects approached, 702 (86%) were finally included in study (mean age 42.67 years; men n = 452 (64.4%), women n= 250 (35.6%). Out of these 3.7% (4.2% men, 2.8% women) were found to be at high risk for OSAS. Out of total studied population, 11.72% men and 14.8% women were obese (BMI 30 kg/m2) and 19.8% of obese population were at high risk for OSAS. Among high-risk patients for OSAS, 42.3% had hypertension. The mean ESS score was 5.17 2.58. Out of 702 subjects, 13 had clinically significant form of OSAS defined as snoring at least 3-4 times/week, EDS (ESS score 11) and obesity (BMI 30 kg/m2), giving overall prevalence of OSAS at least 1.6% comprising 2.4% men and 0.8% women. Statistically significant risk-factors found for OSAS were obesity, large neck size (17 inch in male or 15 inch in female), alcoholism and sedatives/ tranquilizers use. Male gender and smoking were associated with increased risk for OSAS but with no statistical significance.

Conclusion: OSAS is a common disease and there is high demand for its awareness, evaluation, diagnosis and management. Symptoms category 2 of BQ may be replaced with use of ESS score in developing countries like India.

KEYWORDS : Sleep apnoea, Berlin questionnaire, Epworth sleepiness scale score (ESS Score), obesity. Hypertension

INTRODUCTION

The field of snoring and sleep apnoea has grown rapidly in recent years. The obstructive sleep apnoea syndrome (OSAS) is a potentially disabling condition characterised by excessive daytime sleepiness, disruptive snoring, repeated episodes of upper airway obstruction during sleep and nocturnal hypoxaemia. Several community based epidemiological studies from developed countries have provided evidence regarding high prevalence and wide severity spectrum of undiagnosed OSAS and have consistently found that mild or even undiagnosed OSAS is associated with significant morbidities.[1] These studies have revealed that undiagnosed OSAS with or without symptoms, is independently associated with increased likelihood of hypertension, cardiovascular disease, stroke, daytime sleepiness, motor vehicle accidents, diminished quality of life and behavioural changes. Strategies to decrease the high prevalence and associated morbidity of OSAS are critically needed. Estimates of the prevalence of OSAS worldwide including studies from India provide widely different figures ranging from 0.3%-35% probably because of differences in definitions, in the design of the studies and the investigations performed, and in the age, sex and other characteristics of the population surveyed.[1-9] A study done in middle aged urban Indian men of 35-65 years age group, found the prevalence of OSAS 7.5% and of sleep disordered breathing 19.5% in patients who came to hospital for routine health check-up. [9]

The present study was conducted to know the prevalence estimates of key symptoms and features that can indicate the presence of OSAS in the Indian population as the literature is not rich enough regarding this problem for Indians.

MATERIALS AND METHODS

Consecutive apparently healthy attendants in age group of 25-64 years, attending outdoor of King George Medical University, Lucknow, India, were interviewed face to face using pre-tested Berlin questionnaire (BQ) with some relevant modifications (Appendix-1) on a fixed single day in a week from August 2003 to July 2004. Their data were recorded on pre-designed proforma having age, sex, height, weight, neck circumference, and blood pressure. Excessive daytime sleepiness (EDS) was also assessed by Epworth sleepiness scale (ESS).[10] We also tried to assess some risk factors like smoking, alcoholism and use of sedative or tranquilizers. The BQ tool was developed in 1996 and its origin and use in primary care has been reported previously.[11] This is focused on a set of known symptoms and clinical feature associated with sleep apnoea. One introductory question and four follow-up questions concerned snoring, witnessed apnoeas and the frequency of such events. Three questions addressed daytime sleepiness with a sub-question about drowsy driving. One question was asked for a history of high blood pressure. Body mass index (BMI) was calculated from height and weight recorded on proforma. Bilingual physicians translated BQ

from its original English version into Hindi. Translation were performed from Hindi back into English by other bilingual physicians and were consistent with the intent of the original version.

Risk grouping for high-risk and lower risk for OSAS were based on responses grouped into three categories. In category 1, a positive score for high-risk was defined as frequent symptoms (i.e. "more than three to four times per week or almost everyday") in two or more questions about snoring and witnessed apnoeas. In category 2, a positive score for high-risk was frequent symptoms in two or more questions about awakening sleepy or tiredness after sleeping, wake time sleepiness and/or drowsy driving. In category 3, a positive score for high-risk was defined as presence of hypertension and/or obesity (BMI $\geq$ 30 kg/m2). To score "high-risk" for OSAS, an individual's questionnaire should have had positive scores in two of the three categories, or in all three. Those patients who denied having symptoms with such frequency or who qualified in only one category were placed into a lower risk group.[11] The relationship of risk grouping for a high pretest probability was previously shown to have a positive predictive value of 89% and a likelihood ratio of 3.79 for a subsequent finding of a respiratory disturbance index >5 on a sleep study.[11]

Statistical Analysis
To facilitate interpretation, some independent variables were transformed as follows: gender (male/female), BMI (< 30kg/m^2 vs ≥ 30 kg/m^2) and blood pressure (yes/no). Rate differences between genders were calculated by odds ratio (ORs) and the corresponding 95% confidence intervals (CIs). Statistical significance meant that the *p* value of the corresponding statistical test was < 0.05. These parameters also applied for risk factors regarding OSAS.

RESULT
Out of 816 subjects approached 702 (86%) successfully participated in the study and were included for final analysis. Out of these 702, 452 (64.4%) were males and 250 (35.6%) were females. Mean age was 42.7 $\pm$ 10.4 years (men 43.6 $\pm$ 10.2 years, women 40.9 $\pm$ 10.5 years). Mean neck circumference was 13.6 $\pm$ 1.2 inch. Mean BMI was 23.8 $\pm$ 4.2 kg/m^2 and mean ESS score was 5.2 $\pm$ 2.6. Out of 702, 496 (70.7%) were urban and 206 (29.3%) were rural. Urban population was at higher risk than rural population (*p*=0.11). Of 702, 26 (3.7%) were at high-risk for OSAS (qualified two or more category symptoms), comprising 4.2% of men and 2.8% of women (Figure 1). Out of 702, 218 (31.1%) were snorers, 406 (57.8%) were non-snorers and 78 (11.1%) did not know whether they snore (vide Table 1). Among the studied population, 33.8% men and 26.0% women were snorers. Among snorers (38)17.4% were loud snorers and 60.5% of them were at high-risk for OSAS (vide Table 1). The prevalence of OSAS was significantly higher in loud snorers than non-loud snorers. (*p*<0.001) Among snorers, 21.6% snored at least three to four times per week and 53.2% of them were at high-risk of OSAS. The risk of OSAS was significantly higher in those who snored (3-4 times per week) than those who snored (1-2 times per week).(*p*<0.001) Among snorers, 22.9% bothered other people and 46.0% of bothersome snorers were at high-risk of OSAS. Bothersome snorers were at significantly higher risk of OSAS than non-bothersome snorers.(*p*<0.001) Among snorers, 60% were not cared by other to notice breathing pauses and only 40% were cared for the same, 20.5% of those who were cared had breathing pauses (3-4 times per week) and 77.8% of them were at high-risk of OSAS, which was highly significant. (*p*<0.001) Out of 702, 6.0% population had morning tiredness or sleepy awakening (3-4 times per week) and 52.4% of them were at high-risk of OSAS, which was significantly higher than those who had morning tiredness or sleepy awakening less often (1-2 times per week). (*p*<0.001) Out of 702, 5.1% population had wake-time tiredness or sleepiness (3-4 times per week) and 61.1% of them were at high-risk of OSAS, which was highly significant than those who had less often (1-2 times per week). (*p*<0.001) Out of 702, 45.3% did not know to drive or need not to drive and 54.7% used to drive. Among persons who used to drive, 2.1% had drowsiness behind the wheel (3-4 times per week) and 75% of them were at high-risk of

OSAS which was highly significant than those who had drowsiness behind the wheel less often (1-2 times/week). Out of 702, 13.0% were obese, 14.8% were overweight and 72.2% were either healthy or under- weight. Out of 702, 11.7% males and 15.2% females were obese. About 19.8% of the obese population was at high-risk of OSAS. About 24.8% obese males and 13.8% obese females were at high-risk of OSAS. The prevalence of hypertension was 42.3% in those who were at high-risk of OSAS while it was only 4% in others. (p<0.001) In our study of 702 adults, 13 had clinically significant form of OSAS defined as snoring at least 3-4 times per week, having excessive daytime sleepiness (Epworth sleepiness scale score $\geq$ 11) and obesity (BMI $\geq$ 30 kg/m^2), giving overall prevalence of OSAS at least 1.9%, comprising 2.4% in males and 0.8% in females (Figure 1). Out of 702, 40 (5.7%) qualified for category 1 symptoms, 20 (3.2%) qualified for category 2 symptoms and 98 (14%) qualified for category 3 symptoms and about 1.1% had drowsy driving at least 3-4 times/week (vide Table 2). Risk factors for OSAS, with statistical significance were obesity (p<0.001), neck size (17 inch in male or 15 inch in female) (*p*<0.001), alcoholism (*p*<0.001) and sedatives/tranquillizers use. (*p*=0.003) Risk factors with no statistical significance but associated with higher OSAS were male sex (*p*=0.35) and smoking (*p*=0.17). (Vide Table 3)

DISCUSSION
Probably this is the first study conducted among semi-urban Indian population in a wide ranging population of Lucknow, India to know prevalence of OSAS using BQ as previous studies from India were confined to urbanized population with variable demographic profile, belonging to metropolitan cities such as Delhi and Mumbai. In our study, we have taken a population between 25-64 years age group, as most of the patients belonged to this age group. Cut-off age limit of 64 years was taken because above this age the chances of central sleep apnoea are high rather than OSAS which may give false high prevalence of OSAS. We have used pre-tested Berlin questionnaire with some relevant modifications to find out the prevalence of OSAS, while it has been tested for sleep apnoea syndrome by Netzer et. al.[11] Sleep apnoea can be obstructive or central type, but as the study of Bixler et. al. predicted that central sleep apnoea is non-existent before the age of 65 years and occurs in 5% of samples over the age 65 years.[12] So, the use of BQ as instrument in our study of 25-64 years age group population to find out the prevalence of OSAS is justified. We did some relevant modifications in BQ as per the need and circumstances of our country.

Firstly, because in a country like India about half of the population either do not know to drive or need not to drive vehicles, especially villagers and women. Secondly, category 2 symptoms of BQ assess wake time fatigue or excessive sleepiness which may reveal high-risk of OSAS even in diseases like diabetes and heart failure. As sleepiness is a prominent feature of OSAS, which may be better assessed by ESS and also it does not need driving and is based on mainly routine activity, so category 2 of BQ may be replaced with ESS in countries like India, which needs further confirmation by polysomnographic studies.

In our study 3.7% of the population was at high-risk of OSAS, comprising 4.2% men and 2.8% women. Among these the prevalence of clinically significant OSAS defined as snoring at least 3-4 times per week, excessive day time sleepiness (ESS score $\geq$ 11) and obesity (BMI $\geq$ 30 kg/m^2) was 1.9%, comprising 2.4% in men and 0.8% in women. The prevalence of OSAS in our community may be even lower than our study because the persons coming as attendants in our department, a tertiary care centre were mainly males (M: F=1.8:1), more educated and belonging to better socioeconomic status and urban areas. Young et al., also reported similar prevalence like 4% of men and 2% of women had sleep apnoea in their study.[13] Neven et. al. also reported the prevalence of clinically significant sleep apnoea syndrome in men aged 35 years or over was at least 0.45%.[14] Another study done by Udwadia et al., in urban Indians in age group of 35-65 years who came to their hospital for routine

health check-up, showed a prevalence of OSAS ~7.5% which is much higher than our study.[9] The reasons for this higher prevalence might be that it has been done in only males of urban areas, who were better educated and employed having higher income and BMI and having westernized lifestyle. On the other hand, our study includes both males and females and urban as well as rural population. Other studies based on Berlin questionnaire showing much higher risk of OSAS include the study of Netzer *et. al.*, who reported that 37.5% of their population was at high-risk of sleep apnoea syndrome comprising 44.5% men and 33.0% women.[11] In another study, Netzer *et. al.*, reported that 35.8% of US and 26.3% of the European population were at high-risk of OSAS.[15] In these studies the prevalence of obesity was very high and there were more positive way of responding to questionnaire distributed to them, while our study includes face to face interview so that the chances of responding positively was very less and it also brings uniformity. The prevalence of obesity is much less in our Indian population in comparison to the above populations. The prevalence of obesity in our population was 13% while it was 27.9% in USA and 17.2% in the European population. Our study shows significant association between hypertension and OSAS (p<0.001) which has been shown by other studies also.[16-18] In our study, the risk-factors for OSAS with statistical significance were obesity (*p*<0.001), neck size (17 inch in male or 15 inch in female) (*p*<0.001), alcoholism (*p*<0.001) and sedatives/ tranquilizers use (*p*=0.003). Flemons *et. al.*, also reported that even a neck size of 16.141.38 inch was a significant risk-factor for sleep apnoea (*p*<0.001).[19] Many studies[1-9,20-28] have found significant association between OSAS and measures of excess body weight. Many studies[27-33] in which defined quantities of alcohol were administered to healthy subjects or patients with OSAS before bedtime have demonstrated harmful effects on nocturnal respiration including increased number and duration of hypopnoea and apnoea events.

In our study, the risk-factors for OSAS with no statistical significance but associated with higher OSAS were male sex (*p*=0.35) and smoking (*p*=0.17). Many cross-sectional epidemiological studies of OSAS have found positive associations with cigarette smoking.[1,34-37] Wetter *et al.* found that current smokers were three times (95% CI, 1.4 to 6.4) more likely to have OSAS than never-smokers.[37] Another analysis from Sleep Heart Health Studies also found an inverse association between current smoking and OSAS, after adjusting for several factors including age and BMI, current smokers had significantly fewer respiratory disturbance events as assessed by in-home polysomnography.[38] Other risk factors like deviated nasal septum (DNS) / nasal obstruction, tonsillar hypertrophy, macroglossia, retrognathia / micrognathia and endocrine disorders like hypothyroidism or acromegaly could not be studied because of lack of required investigations and further work-up.

Limitations

This study has few limitations. The predictive performance of risk categorization for OSAS (diagnostic accuracy) by modified BQ was not compared to gold standard supervised in-laboratory polysomnography. This is a single centre hospital study as most of the subjects are attendants of patients coming to hospital OPD thereby not representing actual proportion of community therefore the findings has to be generalized by conducting community based surveys that can portray epidemiology with better accuracy. Hospital studies usually recruit patients with a high pre-test probability of diagnosis, which is true for studies using questionnaires/symptomatology studies.

Conclusions

OSAS is a common disease in developing countries like India and there is high demand for its awareness, evaluation, diagnosis and management. This country is heavily populated with diverse social norms and many groups live in an underdeveloped environment. It is practically not feasible to perform gold standard in laboratory supervised polysomnography and even unsupervised portable polysomnography in every patient which is labour intensive and time consuming. Therefore, BQ can screen those subjects with

symptoms of high risk OSAS from this population and can undergo PSG on priority basis for management as compared to subjects with low risk OSAS.

Appendix 1:- MODIFIED BERLIN QUESTIONNAIRE

Do you snore or **you have been told you do?**
• Yes
• No
• Do not know
If Yes:

Category-1 Questions about snoring behavior:
Q-1 Snoring Loudness?
• Loud as breathing
• Loud as talking
• Louder than talking*
• Very loud*

Q-2 Snoring frequency?
• Almost every day*
• 3-4 times/week*
• 1-2 times/week
• 1-2 times/month
• **Never or almost never**

Q-3 Does your snoring bother to other people?
• Yes*
• No

Q-4 How often your breathing pauses been noticed?
• Almost every day*
• 3-4 times/ week*
• 1-2 times/ week
• 1-2 times/ month
• Never or almost never
• **Not cared**

Impression: Whether qualified for CAT-1 symptoms
• Yes * (If persistent symptoms (≥3-4 times/week) in two or more questions).
• No (If denied persistent symptoms)

CATEGORY-2: Questions about wake time tiredness or Day time sleepiness:
Q-1 Are you tired after sleeping?
• Almost every day*
• 3-4 times/week*
• 1-2 times/week
• 1-2 times/ month
• Never or almost never

Q-2 Are you tired during wake time?
• Almost every day*
• 3-4 times/ week*
• 1-2 times/week
• 1-2 times/ month
• Never or almost never

Q-3 Have you ever fallen asleep while driving or **sitting behind wheels?**
• Almost every day*
• 3-4 times/ week*
• 1-2 times/week
• 1-2 times/month
• Never or almost never
• **Non driver (either do not know or need not to drive)**

- *Impression:* Whether qualified for CAT-2 symptoms?
- Yes * (If persistent symptoms (≥ 3-4 times/week) in 2 or more questions.
- No (If denied persistent symptoms)

CATEGORY-3: Questions about obesity or hypertension:
Q-1 Has your weight changed?
Tick whether body mass index BMI (in kg/m²) is
<30
≥30*

Q-2 Do you have high blood pressure?
- Yes* **(history or found on physical examination)**
- No

Impression: Whether CAT-3 symptoms?
- Yes* **(If BMI ≥ 30 kg/m² or presence of hypertension)**
- No
  *High risk

FINAL IMPRESSION
Q-1 Whether Qualified?
- None of the category symptoms
- Only one category symptoms
- Two categories symptoms*
- All the three categories symptoms*

Q-2 Whether subject is on risk of obstructive sleep apnoea?
- High risk (who qualified ≥2 categories symptoms)
- Low risk (Who denied persistent symptoms or qualified for only one category)

(Note: - All Modifications marked in red)

**APPENDIX 2:- Modifications in Berlin Questionnaire as shown in Table 1**
- Indirect way to know snoring status.
- Considered as non-snorer who answered never or almost never for snoring frequency.
- "Not cared" added regarding breathing pauses (about 60% population of our study).
- Modified to know frequency of asleep while driving.
- Non-driver (either don't know or need not to drive) mainly applicable for women and villagers in India.
- In case of unawareness regarding hypertension, blood pressure recorded, but still more relied on history, because it may increase during interview due to anxiety or stress.
- Weight change information was very conflicting, so more relied or body mass index (BMI), calculated from height and weight.

Table-1: Distribution of Responses according to Gender*

Berlin Questionnaire	Men		Women		Total	
	No.	%	No.	%	No.	%
CATEGORY-1						
Do you snore? or you have been told you do?#	452		250		702	
Yes	153	33.8	65	26.0	218	31.1
No	251	55.6	155	62.0	406	57.8
Do not know	48	10.6	30	12	78	11.1
Snoring Loudness	153		65		218	
Loud as breathing	46	30.0	24	36.9	70	32.0
Loud as talking	78	51.0	32	49.2	110	50.5
Louder than talking	18	11.8	5	7.7	23	10.6
Very loud	11	7.2	4	6.2	15	6.9
Snoring Frequency	153		65		218	
Almost everyday	22	14.4	10	15.4	32	14.7
3-4 times/wk	11	7.2	4	6.2	15	6.9
1-2 times/wk	98	64.0	37	56.9	135	61.9

1-2 times/month	22	14.4	14	21.5	36	16.5
Never or almost never@	-	-	-	-	-	-
Does your snoring bother other people	153		65		218	
Yes	38	25.5	11	16.9	50	22.9
No	114	74.5	54	83.1	168	77.1
How often your breathing pauses been noticed	153		65		218	
Almost every day	5	3.3	2	3.0	7	3.2
3-4 times/wk	9	5.9	2	3.0	11	5.0
1-2 times/wk	10	6.5	4	6.3	14	6.4
1-2 times/month	7	4.6	3	4.6	10	4.6
Never or almost never	30	19.6	16	24.6	46	21.2
Not cared§	92	60.1	38	58.5	130	59.6
CATEGORY-2						
Are you tired after sleeping?	452		250		702	
Almost every day	10	2.2	8	3.2	18	2.6
3-4 times/wk	16	3.5	9	3.6	25	3.6
1-2 times/wk	22	4.9	13	5.2	25	3.6
1-2 times/month	34	7.5	18	7.2	52	7.4
Never or almost never	270	59.1	202	80.8	572	81.4
Are you tired during wake time?	452		250		702	
Almost every day	10	2.2	4	1.6	14	2.0
3-4 times/wk	17	3.8	5	2.1	22	3.1
1-2 times/wk	25	5.5	16	6.4	41	5.8
1-2 times/month	39	8.6	26	10.4	65	9.3
Never or almost never	361	79.9	199	79.6	560	79.8
Have you ever fallen asleep while driving? How often you fall asleep while driving?*	452		250		702	
Almost every day	3	0.7	0	0.00	3	0.4
3-4 times/wk	4	0.9	1	0.5	5	0.6
1-2 times/wk	5	1.1	1	0.5	6	0.9
1-2 times/month	24	5.3	4	1.6	28	4.0
Never or almost never	315	69.7	27	10.8	342	48.8
Non-driver• (either do not know or need not to drive)	101	22.3	217	86.8	318	45.3
CATEGORY-3						
Do you have high blood pressure? If unaware, whether hypertensive on examination?♥	452		250		702	
Yes	22	4.9	6	2.4	28	4.0
No	430	95.1	244	97.6	674	96.0
Has your weight changed? Whether BMI is 30 kg/m²?♠	452		250		702	
Yes	53	11.7	38	15.2	91	13.0
No	399	88.3	212	84.8	611	87.0

As per modifications in Berlin Questionnaire given in (Appendix-1 and 2)
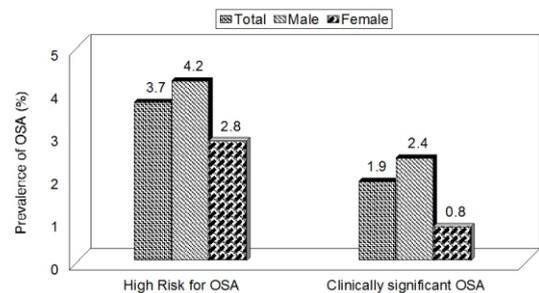
Fig. I: - Total and gender wise prevalence of high risk for OSAS and clinically significant OSAS

Table-2: Risk factors and functional sleepiness between

Genders.

Patients	Patients at high risk		Patients qualifying for category 1		Patient qualifying for category 2		Patient qualifying for category 3		Patient who report persistent drowsy driving	
	No.	%	No.	%	No.	%	No.	%	No.	%
Men (n=452)	19	4.2	30	6.6	16	3.5	60	13.3	7	1.5
Women (n=250)	7	2.8	10	4.0	4	1.6	38	15	1	0.4
Total (n=702)	26	3.7	40	5.7	20	3.2	98	14.0	8	1.1

Table-3: Evaluation of Risk Factors for OSAS

Risk factors	Categories of risk factors	High-risk OSAS patients		Non-risk OSAS subjects		Total		Statistical significance
		No.	%	No.	%	No.	%	
Obesity (BMI30 kg/m2)	+ve	18	69.23	73	10.79	91	12.96	χ^2=75.77, p<0.001, OR=8.59, CI=7.32-48.50
	-ve	8	30.77	603	89.21	611	87.04	
Neck size (17" in male or 15" in female	+ve	10	38.46	11	1.62	21	2.99	χ^2=115.22, p<0.001, OR=37.22, CI=12.47-112.27
	-ve	16	62	665	98.38	681	97.01	
Male sex	+ve	19	73.07	433	64.05	452	64.38	χ^2=.89, p=0.35, OR=1.52, CI=0.60-4.05
	-ve	7	26.93	243	35.95	250	35.62	
Smoking	+ve	12	46.15	228	33.72	240	34.18	χ^2=1.72, p=0.17, OR=1.68, CI=0.72-3.94
	-ve	14	53.85	448	66.28	462	65.82	
Alcoholism	+ve	7	26.92	46	6.80	53	7.54	χ^2=14.50, p<0.001, OR=5.05, CI=1.82-13.54
	-ve	19	73.08	630	93.20	649	92.46	
Sedatives or tranquilizers use	+ve	3	11.53	15	2.21	18	2.56	χ^2=8.69, p=0.003, OR=5.75, CI=1.23-23.33
	-ve	23	88.47	661	97.79	684	97.44	

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