

A Prospective Study of Clinical Scoring versus Polysomnography in Patients of Suspected Obstructive Sleep Apnea attending Pulmonary Medicine Department

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Received: 11-06-2021 / Revised: 30-06-2021 / Accepted: 30-07-2021

Abstract

Introduction: Obstructive sleep apnea (OSA) is characterized by repetitive obstruction of the upper airway often resulting in oxygen desaturation and arousals from sleep. It is associated with various adverse health consequences. Overnight polysomnography (PSG), the gold standard for its diagnosis is expensive and time consuming. Identification of predictors with high likelihood for OSA and then subjecting patient for polysomnography can help in effective resource utilization. **Patients and Methods:** This Institution based prospective study was conducted for 6 months in the Department of Pulmonary Medicine on patients suspected of OSA. We assessed all the clinical predictors of OSA and then subjected patients to overnight gold standard polysomnography test to diagnose OSA. Using statistical test independent predictors of OSA, cut off values of continuous variables were determined to help in prioritizing patient for PSG testing. **Result:** Out of 50 enrolled patients, 44 patients have OSA and 6 do not have OSA. Parameters which had a significant association with OSA were symptoms associated, associated hypertension, neck circumference >40cm, presence of upper airway abnormality, Mallampati score >3, Epworth sleep score of >11, Berlin score with high risk category and STOP BANG score showing high risk. Subsequently cut off values were determined for prioritizing patients for PSG. **Conclusion:** Clinical predictors are helpful in selecting the patients for overnight polysomnography, which may be helpful in early diagnosis of OSA. They may also help to avoid few unnecessary polysomnographies and thus save time and resources.

Keywords: Obstructive Sleep Apnea, Clinical Predictors, Polysomnography

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Introduction

Obstructive sleep apnea is a condition characterized by repetitive obstruction of the upper airway often resulting in oxygen desaturation and arousals from sleep. The main clinical features of OSA include loud, habitual snoring, witnessed apneas, excessive daytime sleepiness (EDS), nocturnal awakening, gasping or choking episodes during sleep, nocturia, unrefreshing sleep, motor accidents, neurocognitive changes and decreased libido. Among these, snoring is found to be the most common symptom. The most daytime symptoms are excessive sleepiness, poor concentration, not feeling fresh in the morning and easy fatigability[1]. The main risk factors for OSA are male sex, obesity, neck size, alcoholism, oral cavity abnormalities such as micrognathia, retrognathia and tonsillar hypertrophy, among which the first three factors are most important. OSA, if untreated is associated with various adverse consequences on the health of the individual, including cardiovascular complications such as hypertension, arrhythmias, pulmonary artery hypertension, congestive heart failure, cor pulmonale, neurological complications such as stroke and sudden death. Several studies have demonstrated

that OSA is an independent risk factor for these events. Hence, an early diagnosis of OSA is essential so that therapeutic interventions can be made at sufficiently early stage itself thereby reducing the morbidity and mortality as well as improving the quality of life. The diagnosis of OSA is confirmed by doing a sleep study or Polysomnography (PSG) which can be either an overnight or a split night study. Overnight Polysomnography (OPS) remains the "gold standard" for the assessment of sleep disorders especially in situations where OSA is suspected. Polysomnography is the electrographic recording of various variables during sleep. From such records, apneas, hypopneas and snoring related arousals are scored. The apnea hypopnea Index (AHI) is calculated from the number of apneas plus hypopneas per hour. Typically, polysomnography requires admission to the hospital with a trained technician present throughout the night. It is time consuming and expensive[2]. It is therefore crucial to identify predictors that will help us to identify subjects with high likelihood of having OSA and then subject these candidates for PSG. This will help in effective resource utilization. Sleep centres using different techniques and equipment and diagnostic criteria make evaluation and comparison of PSG data difficult. Here, our endeavour was to assess the value of the clinical data and anthropometric data for predicting OSA and to find the independent predictors of OSA, if any, in a group of patients with features suggestive of OSA and comparing them with

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polysomnography report so that those clinical predictors can be used as effective tool for diagnosis & treatment of OSA.

The study objectives were 1) To evaluate/assess clinical scoring for diagnosis of OSA based on demographic, anthropometrics and questionnaires variable and to compare the clinical score with PSG.

Patients and Methods

This institution based prospective study was conducted between January to June-2014 in the Department of Pulmonary Medicine at SSG Hospital, Vadodara, Gujarat on patients with suspected obstructive sleep apnea for evaluation of clinical scoring diagnostic system for OSA. The study was conducted with the approval of institutional ethics committee (ECR/85/Inst/GJ/2013).

Patients of age above 15 years with day time sleepiness, obesity, snoring, choking spells and other conditions suggestive of OSA were selected for this study. Patients with severe debility, uncooperative, mentally challenged patients, patient with other sleep disorders, patients below 15 years were excluded from study.

The selected patients were briefed about the nature of study and written informed consent was obtained. A detailed history about snoring, daytime sleepiness, tiredness and easy fatigability, observed apnea and comorbidities was taken. Findings of general physical and systemic examination, demographic and anthropometric parameters were also noted. The clinical predictors of obstructive sleep apnea were assessed using sleep questionnaires such as Epworth's sleep scale, Berlin's sleep scale and STOP BANG sleep scale. In present study 50 patients were enrolled and subjected to overnight polysomnography test. Obstructive Sleep Apnea Syndrome (OSAS) is said to be present when the AHI is greater than 5 to 10 events per

hour and the patient is symptomatic. Finally, accuracy of the clinical scoring in diagnosing and assessing the severity of OSA was evaluated. After the diagnosis, the patients with OSA were classified in to 3 groups according to severity and compared with patients with non-OSA.

The data obtained was analyzed using IBM SPSS v22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). For qualitative data, Chi square test and ROC curve were used.

Results

A total of 50 patients were enrolled, 34 of whom were males. Of these, 44 patients had OSA (34-severe, 6-moderate and 4-mild OSA). Three men and three women did not have OSA. The mean (±SD) age of the patients was 50.06 ± 2.8 years. Of the 50 patients, 35(70%) patients had all four symptoms of snoring, excessive day-time sleepiness, easy fatigability and witnessed apnea. Thirty one (88%) of the 35 patients had severe OSA while 3(8.6%) patients had moderate OSA. Eight patients did not have witnessed apnea but had the remaining three of the four symptoms mentioned above. Of these 8 patients, 2(25%) had severe, 2 patients had moderate, 2 patients had mild OSA and 2 patients were non OSA.

Out of 50 patients, 31 patients had only hypertension, 7(14.5%) patients had hypertension and hypothyroidism, 10(20.83%) patients had hypertension with diabetes mellitus type II and 2 patients had no comorbidity. So out of these 48 patients with comorbidity, 34 patients had severe OSA, 5 had moderate, 3 had mild and 6 had no OSA (Table 1).

Table 1: Demographic Variable of Study Populations

Variables	Categories	Apnea Hypopnea Index				Total	Chi square	p value
		Non OSA	Mild OSA	MOD OSA	SEVERE OSA			
Age Groups	> 50 years	4(15.4)	2(8.3)	3(12.5)	17(70.8)	26(100)	0.796	0.313
	< 50 years	2 (8.3)	2(7.7)	3(11.5)	17(65.4)	24(100)		
Sex	Male	3 (8.8)	3(8.8)	3(8.8)	25(73.5)	34(100)	2.621	0.178
	Female	3(18.8)	1(6.3)	3(18.8)	9(53.3)	16(100)		
Symptoms associated	Snoring with excessive daytime sleepiness	3(42.9)	2(28.6)	1(14.3)	1(14.3)	7 (100)	27.142	<0.001
	Snoring, sleepiness and fatigability	2 (25)	2(25)	2(25)	2(25)	8 (100)		
	All the three plus witnessed apnea	1 (2.9)	0	3(8.6)	31(88.6)	35 (100)		
Co-morbidity associated	Hypertension	5(16.1)			26(83.8)	31(100)	13.2821	0.038
	More than one comorbidity	1 (5.8)			16(94.1)	17(100)		
	No co-morbidity	0 (0)			2(100)	2 (100)		

The present study showed that 32 (64%) patients out of 50 have their neck circumference >40 cm. Of these 32 patients, 25(78.1%) had severe OSA, while among the 18 patients with neck circumference < 40 cm, only 5 patients have severe OSA. Out of 50 patients, 35(70%) patients had upper airway abnormalities either pharyngeal or mandibular abnormalities, 31(62%) patients had pharyngeal wall

abnormality that is bulky lateral pharyngeal wall and 4(20%) patients had mandibular abnormality (retrognathia or micrognathia). Out of these 31 patients with pharyngeal wall abnormality 23 (74.1%) had severe OSA while all the 4 patients with mandibular defect had severe OSA [Table 2].

Table 2: Anthropometric & questionnaires variable of Study Populations

Variable	Categories	Non OSA	Mild OSA	MOD OSA	SEVERE OSA	Total	Chi square	p value
Neck Circumference	> 40 cms	2 (6.3)	3(9.4)	2(6.3)	25(78.1)	32(100)	15.1923.	0.00166
	< 40 cms	5(27.7)	4(22.2)	4(22.2)	5(27.7)	18(100)		
Body Mass Index	18.5-24.9	0 (0)	0	0	3(100)	3 (100)	7.825	0.204
	25-29.9	3(23.04)	1(7.6)	1(7.6)	8(61.5)	13(100)		
	30-34.9	3 (13.0)	2(8.7)	5(21.7)	13(56.5)	23 (100)		
	35-39.9	0 (0)	0	0	6(100)	6 (100)		
	>40	0 (0)	1(20)	0	4(80)	5 (100)		
Upper airway abnormality	Present	1 (2.8)	3(8.5)	4(11.4)	27(77.1)	35(100)	9.64	0.021
	Absent	5 (33.3)	1(6.6)	2(13.3)	7(46.6)	15(100)		
Modified Mallampati Score	1	2 (100)	0	0	0	2 (100)	15.122	<0.001
	2	3(17.6)	2(11.8)	4(23.5)	8(47.1)	17(100)		
	3	1(4.0)	2(8)	2(8)	20(80)	25(100)		

	4	0 (0)	0	0	6(100)	6 (100)		
Epworth Sleep Scale	0-7	0	1	0	0	1	22.02	0.0088
	8-9	3(60)	1(20)	1(20)	0	3(100)		
	10-15	4 (13.3)	3(10)	4(13.3)	19(63.3)	30(100)		
	16-24	0 (0)	0	0	14(100)	14(100)		
Berlin Questionnaire (positive)	Cat 1& Cat 1+2	2(40)	1(20)	1(20)	1(20)	5(100)	11.574	0.010
	Cat 1+2+3	4 (8.9)	3(6.7)	5(11.1)	33(73.3)	45(100)		
Stop Bang Questionnaire	High Risk	4 (8.7)	3(6.5)	6(13)	33(71.1)	46(100)	7.182	0.017
	Low Risk	2 (50.0)	1(25)	0	1(25)	4(100)		

In present study, 47 patients had BMI above 25 kg/m² with maximum number of patients (23 patients) BMI was between 30-34.9 kg/m², and 3 patients had BMI <25 kg/m². Out of these 47 patients with BMI above 25 kg/m², 31 patients had severe OSA while all 3 patients with BMI <25 kg/m² had severe OSA with AHI >30 events per hour (Table 2). Modified Mallampati Classification (MMC) is easy and inexpensive test which can be performed at the bed side to assess the disproportion between skeletal and soft tissue of the neck region compare to imaging of the upper airway. 19(38%) patients had Class I or II, 25(50%) had Class III and 6 (12%) patients Class IV. All the patients with MMC Class IV had severe OSA while out of 25 patients with MMC III, 20 (80%) had severe OSA, and out of 19(38%) patients with MMC Class I or II, 8(16%) patients had AHI >30 events per hour. In the present study, we have used Epworth sleep scale for the EDS dosing scoring. Fourteen patients who had Epworth sleep scale between 16 to 24 had severe OSA. Thirty (60%) patients had score between 10 to 15 and only 5 (10%) patients had Epworth sleep scale < 10 [Table 2]. Berlin questionnaires scale determines the risk for OSA syndrome. Out of 50 patients, 45(90%) patients were positive for Category 1, 2 and 3 which indicates high risk for OSA. And out of these 45 patients, 33(73.3%) patients had severe OSA, 5 (11.1%) patients moderate and 3(6.7%) patients had mild OSA.

STOP BANG questionnaire is another method to determine the risk factor for OSA. Out of 50 patients, 46 (92%) patients were positive for the finding suggestive of high risk. Out of these 46 patients, 33(71.7%) had severe OSA, 6(13%) patients had moderate and 3(6.5%) patients had mild OSA. Four patients out of 50 had positive findings suggestive of low risk for OSA. Among these 4 patients, only 1 patient had severe OSA, 1 mild OSA and 2 patients had no OSA. (Table 2)

The various parameters that were considered for the analysis, their comparative statistical analysis between the two groups and the level of significance was determined using Chi square test. The parameters which had a significant association with OSA were associated symptoms, presence of comorbidities such as hypertension and hypothyroidism, neck circumference >40cm, presence of upper airway abnormality, Modified Mallampati Class III or higher, high Epworth sleep score, Berlin score with high risk category and STOP BANG score showing high risk are statistically significant as p-value of these parameters was <0.05. However, in our study age, sex and BMI did not show statistical significance. After this Receiver Operating Characteristic curves (ROC) were plotted which showed neck circumference of >38cm, Modified Mallampati Class > II, Epworth sleep score >11, BMI >32kg/m², patients having all the 4 symptoms (snoring, excessive day time sleepiness, fatigability, witnessed apnea) had best balance of the sensitivity and specificity. Other variables such as Berlin questionnaire scale, STOP BANG scale, both were statistically significant and were independent predictors of OSA.

Discussion

In the present study, the average age of patients with OSA was 49.5 ±10.2 years similar to the patients in the study by Harilakshmanan et al (49.3 years) and Ajay M Bhandarkar et al (43.56±11.3 years)[3,4].

Male gender predilection (74%) found in our study is also comparable to other studies. Study prevalence of OSA among female in study by Dr Ajay M Bhandarkar et al [4] was 28% which is 26% in our study. Whereas prevalence in male was 56.08% in Dr. Ajay M Bhandarkar et al which is 62% in our study. Several studies have demonstrated gender differences which are due to structural and physiological differences in the upper airway. Women have increased activity of the genioglossus muscle which protects their airway from collapsing during sleep. Female hormones also seem to have a protective role [5,6].

In present study 20.4% of patients with OSA had Diabetes Mellitus (DM) similar to that in the study by A Singh et al (27.3%) [7]. Of the 10 patients with DM in our sample, only one (10%) patient did not have OSA. Since diabetes is a consequence of OSA, patients without diabetes should also undergo polysomnography if there are classical features of OSA. There is a strong evidence to indicate that OSA and the risk of Type 2 DM are associated. Autonomic neuropathy could disturb the control of respiration which leads to breathing abnormalities during sleep. Enhanced sympathetic nervous system activity, intermittent hypoxia, dysregulation of hypothalamo-pituitary axis, altered cytokine and adipokine regulation, and endothelial dysfunction have been proposed mechanisms for dysregulation of glucose metabolism in OSA patients leading to diabetes mellitus.

In our study 15% of patients with obstructive sleep apnoea had hypothyroidism which is comparable with Nuckton et al (12%) [8]. Of the 7 patients with hypothyroidism in our sample, 6 patients had very severe OSA. Since hypothyroidism is a cause for OSA rather than a consequence, hypothyroidism should be ruled out in all OSA patients. Mucoprotein deposition in the upper airway, decreased neural signal to the upper airway musculature, obesity, and depression of respiratory centre leading to abnormal ventilator control are the possible mechanisms which might cause OSA in hypothyroidism. In our study, 63.3% of patients with OSA had hypertension comparable to the study by SK Sharma et al (56%) [9]. The mechanisms which contribute to hypertension in OSA include neurogenic (chemoreflex mediated hypoxic stimulation of sympathetic activity), endothelial dysfunction due to enhanced production of vasoconstrictive and trophic agents such as endothelin, metabolic factors, such as those related to obesity, insulin resistance or hyperleptinemia, and finally OSA induced neuroendocrine activation. Similarly, the average neck circumference of the OSA patients was 40.2 ± 2.4cm (statistically significant) as also observed by S K Sharma et al (40.3 ± 3.1 cm) [9]. Neck circumference of non OSA patients was <40 cm in both studies. Neck circumference increases due to thickness of soft tissue in neck and deposition of fat pads in pharyngeal area leading to narrowing of airway. Since neck circumference is greater in males compared to females, it is an additional risk factor for OSA in men. In the present study, 68.1% of patients with OSA had pharyngeal wall abnormality such as voluminous lateral pharyngeal wall (as comparable to the findings of F.L. Martinho et al - 65.6%) [10]. Mandibular defect such as retrognathia was present in 9.09% of OSA patients. However, all patients who had mandibular defect, had severe OSA with AHI >30 events per hour even though they all had BMI in normal range.

Hence, it is advisable that mandibular abnormalities are ruled out in patients of OSA with normal BMI.

Assessing Modified Mallampati Class is easy and inexpensive and can be performed at the bed side to assess the disproportion between skeletal and soft tissue of the neck region compared to imaging of the upper airway. Our findings were comparable to those of Nuckton et al [8].

Average BMI of patients with OSA was 30.9 ± 7.3 kg/m² in the study by S K Sharma et al, 29.23 kg/m² in the study by Harilakshmanan et al and 32.5 ± 5.4 kg/m² in our study although it did not reach statistical significance [3,9]. Thus, in our study BMI was a poor predictor of OSA, thus emphasizing that OSA is multifactorial and there is a need to suspect OSA in non-obese subjects as well. In our study, all the 3 patients with BMI < 25 kg/m² had severe OSA with AHI > 30 events per hour. The probable reason could be the association of mandibular abnormality was contributing for OSA in these patients.

The average score of ESS was 13.7 ± 3.4 in cases of OSA in our study as against 7.3 ± 4.2 as seen by Surendra Kumar Sharma et al and 9.9 ± 5.3 as seen by John B. Dixon et al [9,11]. The higher ESS score in our study might be because of more number of very severe OSA patients (63.3%) among the 44 patients with OSA in our sample.

In our study 41 (82%) patients out of 50 with high risk Berlin score had OSA, and 4 (8%) patients with high risk had no OSA [11]. Similarly, 95.45% of the patients with high risk for STOP BANG questionnaire is comparable to the study by Douglas Cowan et al (95%)

In the present study age, gender and body mass index did not show any statistically significance possibly because of small sample size. However, it also emphasizes the necessity to suspect OSA in non-obese patients as well.

The selection of the patients based on these predictors and the application of these predictors will help us in avoiding unnecessary polysomnography.

This study concludes that some of the clinical parameters are strong predictors of diagnosis and severity of the obstructive sleep apnea. Cut off values of certain quantitative clinical predictors and statistically significant qualitative clinical predictors will help us to prioritise PSG among patients with symptoms of OSA.

Conclusion

Even though overnight polysomnography remains the gold standard for the confirmation of the diagnosis of obstructive sleep apnea, a high index of suspicion by the treating clinician is required to identify it early enough to prevent significant morbidity.

Neck circumference > 38 cm, BMI > 32 kg/m², patients having all four symptoms (snoring, excessive day time sleepiness, fatigability, witnessed apnea) Epworth sleep scale score of > 11, Modified Mallampati Class > II, Berlin score, STOP BANG score positive for high risk category and presence of upper airway abnormalities either pharyngeal or mandibular are independent predictors of obstructive sleep apnea. These clinical predictors could be helpful in selecting the patients for overnight polysomnography, which may be helpful in avoiding at least a few unnecessary polysomnographies, thus saving

time and resources to a great extent. A larger, prospective study is required to frame clinical scoring which can substitute the use of polysomnography for the diagnosis of SDBs at resource limited health care centres and validate the same.

Acknowledgement

We authors are very much thankful to all patients who are enrolled in this study. We are also thankful to our Medical Superintendent who is always supportive in research activities of institute. We are grateful to our colleague and all resident doctors of our department.

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Conflict of Interest: Nil

Source of support: Nil