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Assessing the risk of Obstructive Sleep Apnea in Type 2 Diabetes Mellitus patients in India

Rajiv Kovila[1,*], Lakshmi Vinuthna Reddy[2], Ansh Marfatia[3]

[1]Diploma Diabetology, MBBS, FRCP, Nanavati Hospital: LIC Colony, Suresh Colony, Vile Parle, Mumbai, Maharashtra, 400056

[2]Samatvam Diabetes Endocrinology and Medical Centre, Samatvam: Science and Research for Human Welfare trust

[3]Montgomery High School , Montgomery High School

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OSA risk in Indian T2DM patients

Corresponding author:

Rajiv Kovila, Diploma Diabetology, MBBS, FRCP, Nanavati Hospital: LIC Colony, Suresh Colony, Vile Parle, Mumbai, Maharashtra, 400056

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Abstract

Background/Aim

Obstructive Sleep Apnea (OSA) is a prevalent disorder characterized by recurrent respiratory disturbances during sleep. Patients with Type 2 Diabetes Mellitus (T2DM) and obesity exhibit a substantial susceptibility to OSA (23%–86%). People with OSA have a high risk of several comorbidities like insulin resistance, cardiovascular disease, depressed mood and hypertension. Thus, the objective was to comprehensively evaluate the risk of OSA among T2DM patients in India.

Materials and Methods

A cross-sectional survey was conducted across four cities in India involving 2,000 T2DM patients. The survey gathered data on patient demographics, clinical endpoints, and estimated the risk of OSA using an app which included the STOP BANG questionnaire. Multivariate logistic regression analysis was used to evaluate the association between OSA risk and key variables such as age, gender, BMI, and HbA1c.

Result

Overall, 63.9% of T2DM patients were identified as high risk and 27.3% were at intermediate risk for OSA development. Results of the multivariate logistic regression demonstrated that patients with high BMI ≥35 had significantly greater odds (OR: 5.70; p<0.00) of developing OSA; males had 2.75 times higher odds (p<0.00) and patients with HbA1c value >8% had higher odds (OR: 1.22; p<0.00) of developing OSA.

Conclusion

OSA risk and prevalence are significantly higher in T2DM patients than in the general population with a notable escalation in patients who are overweight/ obese, older, and have prolonged diabetes duration. Early screening using digitalization with a highly sensitive, cost-efficient, and valid tool like STOP-BANG followed by appropriate intervention for OSA can not only reduce the eventual economic burden but can improve patient outcomes.

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Introduction

According to the International Diabetes Federation (IDF), diabetes has reached epidemic proportions in many developing economies such as India which has about 77 million individuals who are diagnosed with type 2 diabetes (T2DM).[1] This trend is expected to grow with population growth and ageing reaching about 134 million people with T2DM by 2045 constituting to be among the top three countries with the highest burden of diabetes.[2]

Obstructive sleep apnea (OSA) is a common form of disordered breathing characterized by inconsistent, partial, or total obstruction of the upper airways leading to periodic desaturation of hemoglobin oxygen during sleep and persistent agitation during sleep.[3] The condition results in variations in intrathoracic pressure and intermittent decreases or stops in airflow, which can lead to hypoxia, hypercapnia, and repeated awakenings from sleep.[4] Because of inadequate sleep quality, individuals with OSA encounter daytime fatigue, drowsiness, functional limitations, and a general decline in their quality of life.[3] Findings from recent literature estimated that OSA impacts almost 1 billion individuals between the ages of 30-69 years worldwide.[5] In India, the prevalence of OSA is based on several cross-sectional studies across various geographies and varies widely between 23.7% to 95% based on study population, methods, and criteria used for diagnosis.[6] An increasing amount of research indicates a reciprocal relationship between OSA[7] and T2DM, both of which are significant risk precursors for cardiovascular diseases.[8,9] Patients with T2DM have a notably high prevalence of OSA (23%–86%).[10,11] Results from a recent meta-analysis reported that the prevalence of OSA in T2DM patients was 56%. Furthermore, the prevalence of both conditions increases with age, male sex, and body mass index (BMI).[12] Insufficient sleep and disruptions in circadian rhythm have recently been identified as potential contributors to insulin resistance (IR) and the onset of impaired glucose tolerance and T2DM.[13] Unrecognized or poorly managed OSA in individuals with T2DM is linked to an increased risk of both microvascular and macrovascular complications, such as peripheral arterial diseases, nephropathy, retinopathy, and neuropathy. Despite these risks, OSA often goes undiagnosed and untreated among T2DM patients, mainly due to a lack of awareness among both the general public and healthcare providers.[13,14] Guidelines from the IDF and the American Diabetes Association (ADA) recommend routine screening for OSA in all adults diagnosed with T2DM to mitigate the associated diabetes-related complications.[15] Overnight polysomnography is the gold standard test used to diagnose OSA. However, this diagnostic test is costly, laborious, and time consuming which limits the use of this test specifically in resource challenged economies and specific populations such as elderly patients.[16] Owing to the drawbacks of polysomnography, other easy to use and cost-efficient methods have been developed to screen patients for OSA.(17) Among these, the STOP- BANG questionnaire which measures snoring, tiredness, observed apnea, high blood pressure, BMI, age, neck circumference and gender (STOP-BANG) is an easy-to-use, efficient, inexpensive, valid, and reliable alternative screening tool, for OSA.[18] As there is limited data on the presence of OSA in T2DM patients, the main goal of this cross-sectional study was to estimate the risk and severity of OSA in T2DM patients using a digital mobile friendly app which included the STOP-BANG questionnaire.

Materials and Methods

Study design and setting

The study was designed as a cross-sectional observational study which was conducted across outpatient clinics in four cities Mumbai, Pune, Delhi, and Chennai in India. A total of 20 diabetologists

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participated in the study and each diabetologist was responsible for recruiting a total of 100 T2DM patients for screening based on the study inclusion criteria. A total of 2,000 patients participated in the study. Patients were enrolled in the study if they had a diagnosis of T2DM, were > 18 years of age, seeking treatment with the participating doctor for more than three months, could speak and read English, used an Android phone, and agreed to participate in the study. Patients were excluded if they were diagnosed with any other type of diabetes, such as type 1 diabetes or gestational diabetes, had central sleep apnea, severe uncontrolled psychiatric disorders or psychiatric medication, patients with current or previous substance abuse, and patients undergoing bariatric surgery. The study was approved by independent ethics committees located within each city. Informed consent was obtained from participating diabetologists and patients.

Data collection process and tool

Patients were enrolled in the study over a six-month period (i.e. between January 1, 2023 to June 30, 2023). For this study, to facilitate ease of data collection, we developed an app called EQUIP which patients who agree to participate could download on their mobile phones when they were waiting in the outpatient clinic. The app collected data on patient demographic profiles, comorbid conditions, medical history, and included the STOP-BANG questionnaire as a screening tool for OSA. Patients entered their demographic and clinical data such as hypertension, duration of diabetes, serum creatinine values, cholesterol levels, HbA1c values, fasting plasma glucose, and medical history (previous cardiovascular problems such as myocardial infarction (MI), coronary artery bypass graft (CABG), obesity, and kidney disease) from their medical chart records in the EQUIP app.[19,20] Anthropometric measurements including height, weight, BMI, waist circumference, hip circumference and neck circumference were recorded in the clinic and entered in the app. Using responses provided by patients on the STOP-BANG questionnaire the EQUIP app calculated an OSA severity score for each individual patient which assisted in categorizing the patients into one of the three risk groups: low risk (score: 0–2), intermediate risk (score: 3–4), and high risk (score: 5–8). [21] Participating patients were assigned a patient identification number to protect their confidentiality and all data was stored on a password protected server.

Statistical analysis

Data were analysed using SPSS 20.0. Categorical variables are represented as percentages and continuous variables as mean ± standard deviation Risk of OSA was also analysed based on duration of diabetes (<5 years, 5-10 years, 10-15 years, 16-20 years, and > 20 years). Risk factors for OSA were evaluated using logistic regression. A value of $P < 0.05$ was considered statistically significant.

Results

Demographic and clinical characteristics of patients

The study included a total of 2,000 patients diagnosed with T2DM. Among these patients' majority 64.75% were males. Mean age of the patient population was 59.1 (S.D. ±9.36) years, of which 80.80% of the patients were over the age of 50. Out of 2,000 T2DM patients, 46% patients had a BMI index of 35 and above and about 41% patients reported to have a prior incident of MI. Blood pressure (83.45%), heart problem (57.75%), obesity (61.30%), and kidney disease (41.30%) were the most reported comorbid conditions. About half the patient population (49.65%) had HbA1c values >8 mg/dl and majority patients 84.30% had fasting plasma glucose level >125 mg/dl. The demographic and clinical characteristics are presented in Table 1.

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Table 1. Demographic and clinical characteristics of patients with T2DM [20]

Parameters	**Total (n = 2000)**	**%**
Age (years), mean (SD)	59.1 (±9.36)	
Gender		
Male	1295	64.75
Female	705	35.25
Duration of Diabetes		
< 5 years	449	22.45
5-10 years	912	45.60
10-15 years	334	16.70
16-20 years	187	9.35
> 20 years	118	5.90
BMI (kg/m2)		
<25	293	14.65
25-34	967	48.35
35-39	730	36.50
≥40	193	9.65
Medical history		
Blood pressure	1669	83.45
Heart problem (prior MI, CABG, etc)	1155	57.75
Kidney disease (based on creatine values)	826	41.30
Other conditions (unspecified)	166	8.30
Systolic Blood Pressure (SBP)- (mmHg)		
<100	117	5.85
100-139	829	41.45
140-159	857	42.85
≥160	197	9.85
Diastolic Blood Pressure (DBP)-(mmHg)		
<60	125	6.25
60-80	838	41.90
≥80	1037	51.85
Fasting Plasma Glucose (FPG)-(mg/DL)		
<125	310	15.50
125-199	1148	57.40
200-299	482	24.10
≥300	60	3.00
HBA1C (mmol/mol or %)		
<6.4%	79	3.95
6.5%-8%	885	44.25

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>8%	993	49.65
Missing Values	43	2.15
High Density Lipoprotein Cholesterol (HDL-C)-(mg/DL)		
≤30	406	20.30
30-59	1344	67.20
≥60	250	12.50
Neck circumference		
<40 cm	1003	50.15
≥40 cm	997	49.85

Risk of OSA assessed with the STOP-BANG questionnaire

The patients who scored ≥5 on the STOP-BANG questionnaire were at a high risk of developing OSA, intermediate risk if they scored between 3-4 and had a low risk if they were marked 0-2 on the scale. (Figure 1) 1278 patients (63.90%), 547 patients (27.35%) and 175 patients (8.75%) were at high, intermediate and low risk of developing OSA accordingly, as per the scores. (Figure 2) The overall median score of the OSA risk for 2,000 T2DM patients were five out of eight indicating that more than half of the patients were at higher risk of OSA. Patients who were male (64.05%), were greater than 50 years of age (80.80%), had received prior treatment for high blood pressure (79.65%), reported feeling tired or fatigued during daytime (75.85%), and had snoring as a symptom (66.00%) were at risk of developing OSA (Table 2). We also grouped T2DM patients according to time since diagnosis of T2DM and assessed their potential risk of developing OSA. About 70.30% patients diagnosed with T2DM for a period of 16-20 years were at a higher risk of developing OSA followed by 69.49% (394 patients) diagnosed with T2DM for 10-15 years (Figure 3). Furthermore, based on findings from

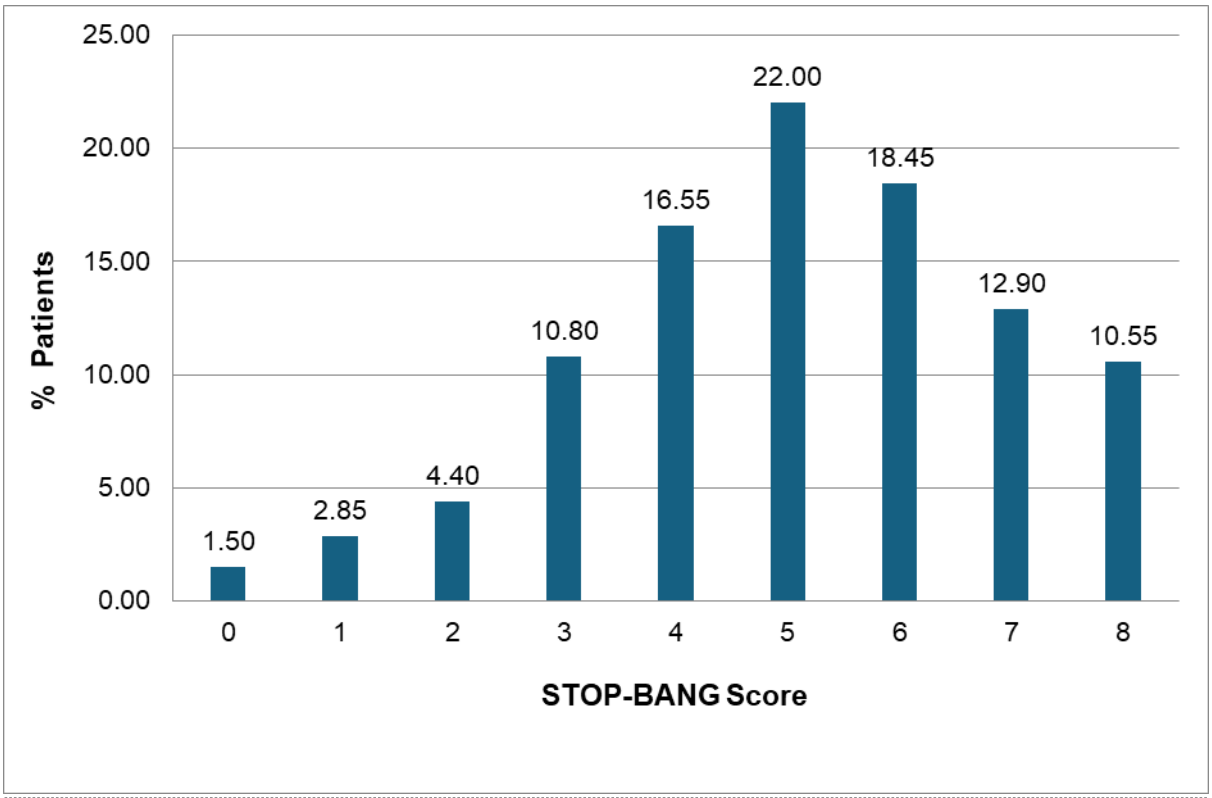

Figure 1. Distribution of STOP-BANG score in T2DM patients

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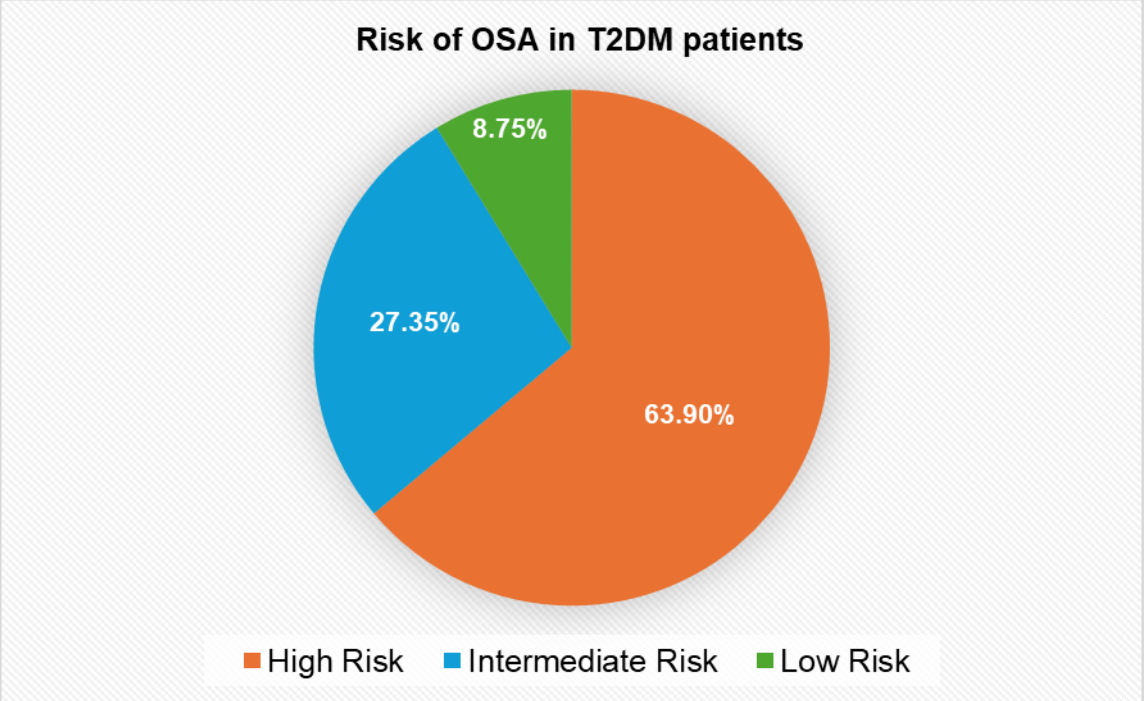

Figure 2. Risk of developing OSA in T2DM patients

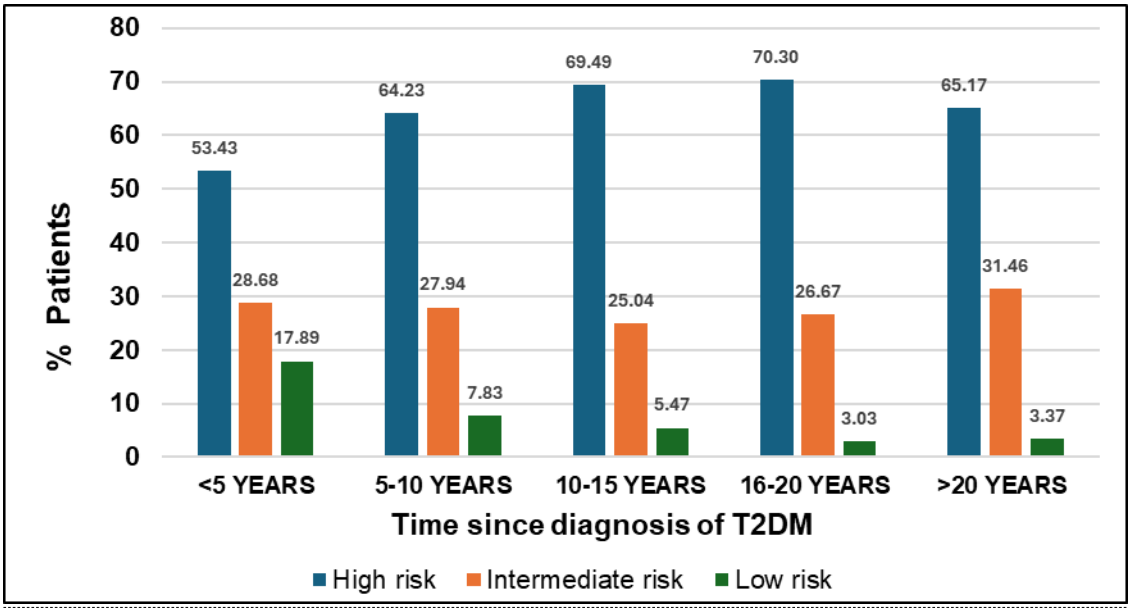

Figure 3. Percent patients as per different OSA scores category according to time since diagnosis of T2DM

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Table 2. Risk of OSA based on findings from the STOP-BANG questionnaire [20]

Variables		**n (%)**
Do you SNORE loudly (louder than talking or loud enough to be heard through closed doors)?	Yes	1320 (66.00)
Do you often feel TIRED, fatigued, or sleepy during the daytime?	Yes	1517 (75.85)
Has anyone OBSERVED you stop breathing during your sleep?	Yes	842 (42.10)
Do you have or are you being treated for high blood PRESSURE?	Yes	1593 (79.65)
BMI more than 35 kg/m^2?	Yes	963 (48.15)
AGE over 50 years old?	Yes	1620 (81.00)
NECK circumference >16 inches (40 cm)?	Yes	978 (48.90)
GENDER: Male?	Yes	1281 (64.05)

Table 3. Multivariate logistic regression to assess the association between age, gender, BMI, HbA1c and OSA risk level among T2DM patients

Covariates	OR (95% CI)	p-value
BMI (kg/m^2)		
<25	1	-
25-34	1.93 (1.46-2.55)	0.00
35-39	5.70 (4.15-7.82)	0.00
≥40	8.65 (4.55-16.46)	0.00
Gender		
Female	1	-
Male	2.75 (2.23-3.39)	0.00
HbA1c (%)	1.22 (1.12-1.33)	0.00
Age (years)	1.04 (1.03-1.05)	0.00

multiple logistic regression several key factors were associated with an elevated risk of OSA among T2DM patients. As reported in Table 3, males exhibited 2.75 times higher odds of OSA risk compared to females, emphasizing the gender-based susceptibility. Age was also identified as a significant factor, with each one-year increase raising the odds of OSA risk by 1.04. Lastly, BMI emerged as a critical determinant, with T2DM patients having BMI ≥40 facing a substantially elevated risk for developing OSA (OR = 8.65, p = 0.00). Similarly, patients with HbA1c levels exceeding 8% were also at an increased risk of developing OSA.

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Discussion

The results from this study, utilizing an app-based STOP-BANG questionnaire, indicate a high OSA risk among T2DM patients, significantly influenced by elevated BMI, HbA1c, and systolic blood pressure. The frequent occurrence of comorbid conditions such as obesity, hypertension, and dyslipidemia emphasize the metabolic interplay between T2DM and OSA. Furthermore, the trend of increasing OSA risk with prolonged diabetes duration highlights the importance of sustained preventive care in T2DM management. Advanced age, particularly in patients over 50, was strongly associated with OSA risk, likely due to physiological aging effects that heighten susceptibility to sleep disturbances. These insights underscore the need for age-specific, long term screening and management strategies to enhance outcome for T2DM patients at high risk of OSA.

The findings of our study can be compared with results from other published literature. A research undertaken by Algeffari et al. in 201 T2DM patients employing the Berlin questionnaire to assess the OSA risk found that 44.3% patients were identified as having high likelihood of developing OSA.[22] The study also documented that higher BMI (OR=3.9; 95% CI=1.4, 7.8, p= <0.001) and longer duration since diagnosis of diabetes (OR=3.1; 95% CI =1.3, 7.8, p= 0.837) were associated with an increased OSA risk. These results align with our findings suggesting that longer duration of diabetes and a high BMI may have a significant influence on elevating the risk of OSA in T2DM patients. Another study conducted in Iran, included a sample of 4,021 participants, with 239 diabetic patients utilized the STOP-BANG questionnaire.[23] This study revealed that 78.6% of the diabetic patients were classified as high risk for developing OSA, in contrast to 35.1% of participants without diabetes. Another cross-sectional study conducted by Shnaimer et al. at the Armed Forces Hospital in Jazan involving 306 T2DM patients-revealed that the median score of the OSA risk level assessed by the STOP- BANG items was 3 on a scale of 0 to 8, of which 63.1% of the participants were classified as being at high risk of developing OSA.[24] Furthermore, a meta-analysis and systematic review conducted by Fallahi et al. assessed the OSA prevalence among 2,360 Iranian patients with diabetes. [25] Their analysis revealed an overall OSA prevalence of 54.5% in T2DM patients with a higher prevalence observed among females (66.22%) compared to males (63.26%). These findings are like the findings from our study. Comparisons with other published literature underscores the consistency of our findings regarding the effect of high BMI and longer diabetes duration on increasing the OSA risk in T2DM patients.

Finally, it is important to note that several studies have validated the use of the STOP-BANG score as a tool for OSA screening. For example, in a study by Chung *et al.* with 310 obese Canadian patients found that a STOP-Bang score of 4 had high sensitivity (87.5%) and had high negative predictive value (90.5%) for identifying severe OSA.[26] In another study conducted in the Korean population, Kim *et al.* reported that the STOP-Bang questionnaire had high sensitivity (97% for AHI $\geq$ 5/h and 98% for AHI $\geq$ 15/h) for OSA screening in those with suspected OSA.[27] These findings combined with our current results strongly support the notion that the STOP-Bang questionnaire is a useful tool for OSA screening in different populations. We would also like to emphasize that using the EQUIP app enabled us to reach a larger pool of patients, eased data collection process in outpatient clinics, and improved accuracy of data by reducing missing data as well as data entry errors.

Future efforts should focus on raising awareness among clinicians and patients about the importance of diagnosing OSA and its connection to T2DM and related complications. OSA is a significant risk factor for cardiovascular and renal disease specifically in patients with T2DM, yet many cases remain

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undiagnosed due to lack of symptoms. With rising age and obesity, routine screening is essential to reduce the health and economic burden of OSA. Integrating user-friendly digital OSA screening tools into routine clinical practice can enhance early detection and improve patient outcomes for T2DM patients. Future studies should focus on treatment and long-term follow-up in these patients to evaluate the benefits of diagnosing OSA.

Limitations

The study's limitations encompass the absence of polysomnography, considered the gold standard confirmatory test for diagnosing OSA. Nevertheless, the STOP-BANG questionnaire's high sensitivity and specificity render it a commendable screening tool for OSA. Furthermore, due to the study's cross-sectional design, the evaluation of OSA risk's impact on diabetes control and outcomes was not explored. Also, the study did not have a control arm (i.e. participants with no T2DM) to assess the risk of OSA and was conducted in India thereby limiting the generalizability of its results to the geography. Lastly, the study did not assess hypothyroidism, a secondary cause of OSA, within the recruited sample.

Conclusion

This pan-India survey highlights the significant association between T2DM and OSA risk, underscoring the urgent need for early screening and intervention. Identifying at-risk individuals facilitates timely management of OSA and related comorbidities such as obesity, hypertension, and other cardiovascular disease, ultimately enhancing patient outcomes. A multidisciplinary approach that integrates sleep health assessments into diabetes care is essential for addressing the complex interplay between these conditions. Such an approach can improve the quality of life for individuals with T2DM by mitigating the adverse effects of OSA and associated health issues. In conclusion, the STOP-Bang questionnaire has demonstrated high sensitivity for OSA screening and severity assessment among diabetic patients, thereby supporting its use as a potentially important screening tool for early identification of OSA.

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