Original Article

PREVALENCE OF SLEEP APNEA IN A POPULATION OF ADULTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

Objective: To assess the prevalence of sleep apnea (SA) in adults with type 2 diabetes mellitus (T2DM) and examine whether demographics and comorbid factors were associated with SA in this population.

Methods: This study enrolled 330 consecutive adults with T2DM referred to a diabetes clinic, 279 of whom completed the study. Evaluation of the presence of SA was performed with use of a single-channel recording device that measures disordered breathing events from a nasal cannula airflow signal. The device was worn by the study participants in their home, after instruction in appropriate use by clinical staff at the diabetes center. The presence and severity of SA were determined by use of an apnea-hypopnea index (AHI), reflecting periods of diminished and absent breathing. Demographic and medical information data were collected to detect factors associated with SA in this study population. In addition, a time and cost analysis was conducted regarding the screening process for SA by clinical staff at the diabetes center.

Results: The results show a high prevalence of SA in adults with T2DM, ranging from 48% (AHI level of ≥10 events/h) to 29% (AHI level of ≥20 events/h). At an AHI cutoff value of ≥15 events/h, the overall prevalence rate was 36% (49% in male and 21% in female participants). The following variables were associated with SA: age ≥62 years, male sex, body mass index ≥30 kg/m^2, snoring, and reports of stopping breathing during sleep. The time and cost analysis showed that the screening device involved minimal setup time, was simple to use, and was a cost-effective method to screen for SA.

Conclusion: SA is a common disorder associated with major morbid conditions, including hypertension, obesity, cardiovascular disease, and insulin resistance. Predisposing factors for SA and T2DM are similar. This study showed that SA has a high prevalence in adults with T2DM and identified factors that may be associated with its presence in this population. Assessment for SA can be easily performed in an outpatient setting with a portable recording device such as the one used in this study. Screening for SA should be considered in the T2DM population. **(Endocr Pract. 2007;13:355-362)**

Abbreviations:
A1C = hemoglobin A1c; **AHI** = apnea-hypopnea index; **BMI** = body mass index; **CPAP** = continuous positive airway pressure; **ECG** = electrocardiogram; **PSG** = polysomnography; **RN** = registered nurse; **SA** = sleep apnea; **T2DM** = type 2 diabetes mellitus

INTRODUCTION

One of the most common types of sleep disturbance is sleep apnea (SA), characterized by periods of decreased breathing (hypopnea) or absent breathing (apnea) during sleep, attributable to obstruction of the upper airway. This disorder affects at least 10 to 20 million adults in the United States (1) and is more common in persons who are overweight or obese than in those who are of normal weight (2). SA is associated with snoring, poor sleep quality, excessive daytime sleepiness, and decreased quality of life (3,4). The presence and severity of SA are defined by an apnea-hypopnea index (AHI), in conjunction with symptoms. An AHI of 5 events/h or greater is usually considered diagnostic of SA. More severe apnea (AHI of ≥15 events/h) has been demonstrated to be associated with a doubling of the risk for the development of hypertension, when adjustments are made for comorbid risk factors such as body mass index (BMI), alcohol use, and cigarette smoking (5).

Type 2 diabetes mellitus (T2DM) affects approximately 5.1% of the adult population in the United States,

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and another 2.7% of cases remain undiagnosed (6). Both obstructive SA and T2DM are more common in persons with obesity than in their normal-weight counterparts and are associated with increasing age and cardiovascular disease. Although some studies have demonstrated an increased prevalence of SA in patients with T2DM, they were performed with use of small samples or male subjects only (7-9).

The primary aim of the current study was to assess the prevalence of SA in a group of adults with T2DM. A secondary aim was to ascertain whether clinical variables, such as BMI, may be associated with the presence of SA in this study population. Another aim was to evaluate the time and cost related to use of a screening device in a diabetes clinical practice.

PATIENTS AND METHODS

Study Participants

All study participants had a diagnosis of T2DM and were required to sign an informed consent document before beginning the protocol. The study was approved by an institutional review board.

Patients were excluded from the study if they had a current diagnosis of SA or were using continuous positive airway pressure (CPAP) therapy. Other exclusion criteria were type 1 diabetes, severe pulmonary or cardiac disease, and use of medications that were known to affect sleep.

Four hundred forty consecutive patients presenting to the diabetes clinic were invited to participate in the study, of whom 330 consented. Although no data were collected on the patients who chose not to participate in the study, there appeared to be no selection bias regarding study participation. Consecutive patients were asked to participate, and those declining gave reasons primarily of time constraints and lack of accessibility to the sleep center or clinic.

Experimental Protocol

Study participants were asked to wear an ApneaLink (ResMed Corp, San Diego, CA) screening device for SA overnight in their home. The first 60 participants were also asked to undergo an attended overnight sleep study at a sleep center, during which polysomnography (PSG) was used simultaneously with the ApneaLink device. PSG is considered the "gold standard" test in the field of sleep medicine for definitive diagnosis of SA (10). The PSG was completed within 2 weeks of the at-home ApneaLink study and was performed for further validation of both the ApneaLink technology and the prevalence data. The diagnosis of SA was based on the AHI obtained from the ApneaLink device after the overnight at-home study. The AHI is based on the total number of episodes of apnea and hypopnea that occur during sleep, or during study time when measurements during sleep are unavailable, divided by the total sleep or study time.

Data were collected regarding diabetes medications, number of years since diabetes was diagnosed, hemoglobin A1c (A1C), cholesterol, triglycerides, and blood pressure. Cholesterol, triglycerides, and A1C results had been obtained during the previous 3 months or, if not available, blood specimens were obtained to determine these results. The BMI was recorded at the time of the initial screening study. Information regarding the presence of asthma, breathlessness, allergies, and a history of cardiovascular disease was also obtained at the initial visit.

Before using the ApneaLink device in their home, study participants were instructed in its use by staff at the diabetes center. They were shown how to wear and operate the device and were also given written instructions to take with them.

ApneaLink Screening Device

The ApneaLink is a single-channel screening device for SA. The device consists of a nasal cannula attached to a small case that houses a pressure transducer; it is held in place by a belt worn around the user's chest (Fig. 1).

The device operates on battery power, has a sampling rate of 100 Hz, a 16-bit signal processor, and an internal memory storage of 15 MB. It has the capacity for approximately 17 hours of data collection.

The ApneaLink software allows analysis of the data and is based on the airflow signal. Analysis of data is performed automatically by the software's algorithm, which produces a 1-page report for review by the clinician. The device also allows full disclosure of the recorded data for review and rescoring if necessary. The default settings of the ApneaLink for episodes of apnea and hypopnea were used in this study. An apneic episode was defined as a decrease in airflow by 80% of baseline for 10 seconds or

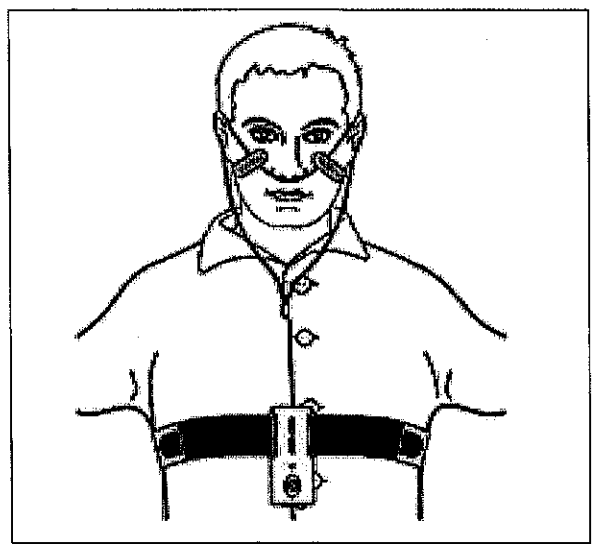

Fig. 1. Diagram of ApneaLink screening device for sleep apnea. See text for further details.

more, and an episode of hypopnea was defined as a decrease in airflow by 50% to 80% of baseline for 10 seconds or more.

In this study, we used 2 hours or more of study time as a cutoff for data analysis. It is common when studying patients with SA to require a minimum of 4 hours of sleep time. To confirm the validity of the 2-hour results with ApneaLink at home, we compared the results with data obtained during a recording time of 4 hours or longer in the sleep laboratory (11).

Statistical Analysis

The prevalence of SA was determined from the ApneaLink results at AHI levels of ≥5, ≥10, ≥15, and ≥20 events/h with use of confidence interval testing. The analyses were done for 2 or more hours of study time. We also report prevalence rates using the AHI results from the PSG study.

Analysis of time and cost variables was performed by evaluation of the time required by clinical diabetes staff to set up the device, instruct the patient in use of the device, and generate the ApneaLink report. A simple model was constructed to compare the labor cost for performing the ApneaLink test with the labor cost for obtaining an electrocardiogram (ECG), a commonly performed test in clinical practice. The model applies the estimated times to perform each component of the 2 procedures to national hourly wage and benefit rates. Users can select wage rates based on 3 skill levels—nursing assistant; licensed practical nurse or licensed vocational nurse; or registered nurse (RN). Hourly wages for 2004 and average fringe benefit rates as a percentage of the total were determined for the 3 categories. The source of wage rate data was the US Bureau of Labor Statistics National Compensation Survey, whereas fringe benefits were as reported by the Bureau of Labor Statistics Employer Costs for Employee Compensation Survey (12,13).

Validation of the ApneaLink findings against PSG results has been previously reported (11,14). Erman et al (11) found a high level of sensitivity and specificity of the ApneaLink compared with PSG in subjects with T2DM.

RESULTS

Prevalence of SA

Of the 330 patients who consented to participate in the study, 279 (146 male and 133 female study participants) had 2 or more hours of recorded evaluable data for assessment of the prevalence of SA. Demographic information is presented in Table 1. The mean age of these 279 patients was 57 years (range, 21 to 82), and the mean BMI was 33.5 kg/m^2 (range, 20 to 69). Of the overall study cohort, 60% were 55 years of age or older. Prevalence rates of SA at all tested AHI values are shown in Table 2. These results demonstrate a high prevalence of SA, ranging from 48% at an AHI of ≥10 events/h to 29% at an AHI of ≥20 events/h. At AHI levels of ≥15 events/h and ≥20 events/h, the SA rate was much higher for male than for female study participants (49% versus 21% and 42% versus 15%, respectively). The prevalence rates for SA obtained during the PSG study in 62 study participants are outlined in Table 3 and confirm the high prevalence rate determined by the ApneaLink from the study performed in each patient's home.

Independent Factors Associated with SA

Medical history data and characteristics of study participants are summarized in Tables 4 and 5. Male sex was independently and highly associated with SA for all AHI cutoff levels of ≥10 events/h (P<0.0001) and borderline nonsignificant for an AHI of ≥5 events/h (P = 0.05). Age of ≥62 years was highly associated with SA for AHI cutoff values of ≥5 events/h (P<0.0001), ≥10 events/h (P = 0.0005), and ≥15 events/h (P = 0.01). BMI was significantly associated with SA at an AHI level of ≥15 events/h (P = 0.02). Snoring and reports of stopping breathing during sleep were also significantly associated with SA for AHI cutoff levels of ≥10, ≥15, and ≥20 events/h. No associations were found between SA and abnormal values of triglycerides, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, or A1C, although only 70% of the study participants had these laboratory results.

Time and Cost Analysis

Another objective of the study was to perform a time and cost analysis related to the use of the ApneaLink and to obtain clinical impressions regarding ease of use for the device. The usual clinical diabetes staff was involved in setup for each study participant and downloading of the ApneaLink results. They recorded the time required to perform each in-office step of the ApneaLink test. Additionally, the respondents rated ease-of-use and compared technical requirements with common in-office diagnostic procedures. The ApneaLink was rated as an "acceptable" device (3 on a 1 to 3 scale) for the diagnosis of SA. The complexity of the device was comparable to performing an ECG. Required time, on average, was less than 12 minutes to perform the 3 steps constituting the ApneaLink test (device setup, patient instruction, and report generation). A learning effect was observed. The total time was reduced by almost 5 minutes when the average time was compared for performing the initial 20% of the procedures versus the final 20% of the procedures.

With use of the economic model and references previously described, hourly wages were determined, ranging from a low of $10.00 per hour (nursing assistant) to a high of $25.96 per hour (RN), and the average fringe benefit rate was 28%. On the basis of model results, the labor cost is approximately equivalent for performance of the ApneaLink test and an ECG. For example, with use of the national hourly wage for a RN ($33.23, including fringe benefits), the cost to perform an ApneaLink test is about $6 (10 minutes to perform complete test) versus approximately $4 to perform an ECG test (7 minutes for comple-

Table 1
Demographic Information for 279 Study Participants, Based on 2 or More Hours of Study Time for Assessment of Prevalence of Sleep Apnea

Factor	Patients* % (no.)
Age (yr)	
Mean ± SD	57.2 ± 12.0
Range	21-82
Age (yr): frequency grouping	
<45	15 (42)
45-54	25 (70)
55-64	30 (83)
≥65	30 (84)
Ethnicity	
Asian	5 (15)
Black	11 (31)
Pacific Islander/native Hawaiian	0.4 (1)
White	67 (188)
Hispanic	14 (39)
Other	2 (5)
Body mass index (kg/m²)	
Mean ± SD	33.5 ± 7.6
Range	19.8-68.6
Sex	
Male	52 (146)
Female	48 (133)

*Except where indicated otherwise.

Table 2
Prevalence Rates and 95% Confidence Intervals for Sleep Apnea, Based on 2 or More Hours of Study Time (N = 279)*

Apnea-hypopnea index (events/h)	All (N = 279) % (no.); 95% CI	Male (N = 146) % (no.); 95% CI	Female (N = 133) % (no.); 95% CI
≥5	72.4 (202)	77.4 (113)	66.9 (89)
	66.8-77.6	69.8-83.9	58.2-74.8
≥10	48.4 (135)	60.3 (88)	35.3 (47)
	42.4-54.4	51.9-68.3	27.3-44.1
≥15	35.8 (100)	49.3 (72)	21.1 (28)
	30.2-41.8	41.0-57.7	14.5-29.0
≥20	29.0 (81)	41.8 (61)	15.0 (20)
	23.8-34.7	33.7-50.2	9.4-22.3

*CI = confidence interval.

Table 3
Prevalence Rates and 95% Confidence Intervals for Sleep Apnea in Polysomnography Cohort (N = 62)*

Apnea-hypopnea index (events/h)	All (N = 62) % (no.); 95% CI	Male (N = 31) % (no.); 95% CI	Female (N = 31) % (no.); 95% CI
≥5	71.0 (44)	80.7 (25)	61.3 (19)
	58.1-81.8	62.5-92.6	42.2-78.2
≥10	50.0 (31)	61.3 (19)	38.7 (12)
	37.0-63.0	42.2-78.2	21.9-57.8
≥15	38.7 (24)	48.4 (15)	29.0 (9)
	26.6-51.9	30.2-66.9	14.2-48.0
≥20	32.3 (20)	38.7 (12)	25.8 (8)
	20.9-45.3	21.9-57.8	11.9-44.6

*CI = confidence interval.

tion) (12,13). The failure rate (defined as noncapture of data for an evaluation period of 2 hours) of the ApneaLink was very low at 15%.

DISCUSSION

This is the first prospective study assessing the prevalence of SA in male and female adults with T2DM in a typical diabetes clinic. The results demonstrate a high prevalence of SA in men and women of all ages, and especially in older men. This finding seems to be consistent with results in prior studies. Katsumata et al (7) found that the prevalence of SA was higher in a diabetic male population in comparison with a nondiabetic male population in a study of 12,787 subjects. Chasens et al (15) found a very high incidence (65%) of undetected SA in patients with T2DM and nocturia. In a study of men with hypertension, Elmasry et al (16) found a prevalence rate of SA of 36% in patients with diabetes in comparison with 14.5% in normoglycemic control subjects.

Sleep apnea is more common in men than in women and is also associated with aging, a higher BMI, and reports of witnessed apneic episodes during sleep (17,18). These associations were also found in the current study population. In addition, reports of snoring were found to be associated with SA. Of those patients with SA, the women were older and had a higher BMI than did the men, but the prevalence rate remained higher in the male study

Table 4
Medical History Information for Study Participants

History	Patients* % (no.)
Sleep characteristics	
Frequent snoring	89 (201 of 227)
Excessive sleepiness	50 (135 of 271)
Breathless at night	19 (50 of 269)
Stop breathing at night	23 (58 of 257)
Not refreshed after sleeping	66 (178 of 269)
Years since diagnosis of type 2 diabetes	
Mean ± SD	7.4 ± 7.6
Range	<1-47

*Except where indicated otherwise.

Table 5
Associations Between Sleep Apnea and Characteristics of Study Participants*

Variable	Apnea-hypopnea index (events/h)			
	≥5	≥10	≥15	≥20
Male sex	$P = 0.05$†	$P<0.0001$	$P<0.0001$	$P<0.0001$
Race	NS	NS	NS	NS
Age ≥62 yr	$P<0.0001$	$P = 0.0005$	$P = 0.0132$	NS
Body mass index ≥30 kg/m²	NS	NS	$P = 0.0207$	NS
Years since diagnosis of diabetes	NS	NS	NS	NS
Diabetes characteristics	NS	NS	NS	NS
Snoring	NS	$P = 0.0007$	$P = 0.0010$	$P = 0.0066$
Sleepiness	NS	NS	NS	NS
Breathless	NS	NS	NS	NS
Stop breathing	NS	$P = 0.0215$	$P<0.0001$	$P<0.0001$
Triglycerides	NS	NS	NS	NS
High-density lipoprotein	NS	NS	NS	NS
Low-density lipoprotein	NS	NS	NS	NS
Hemoglobin A1c	NS	NS	NS	NS

*NS = not significant.
†Borderline nonsignificant.

participants. Excessive daytime sleepiness is common in patients with both SA and obesity (19), although it was not statistically associated with SA in the current study. Because only 70% of our patients had laboratory results completed, the conclusions regarding lack of correlation between laboratory variables and SA must be qualified.

Insulin resistance, which is involved in the pathogenesis of T2DM, has been linked to SA, with several studies demonstrating independent associations among SA, insulin resistance, and impaired glucose metabolism (20-22). Ip et al (20) found that SA was associated with insulin resistance in 270 study subjects independent of obesity, and Punjabi et al (21) demonstrated similar results in 150 men. As part of the Sleep Heart Health Study, a National Institutes of Health-funded project assessing the effect of SA on cardiovascular outcomes (23), Punjabi et al (24) found an independent association between SA and glucose intolerance and insulin resistance in 2,656 study subjects. In a cross-sectional study, Reichmuth et al (25) found that self-reported diabetes was more prevalent in 1,387 study subjects with an AHI level of ≥15 events/h than those with an AHI value of <5 events/h, after controlling for shared risk factors such as age, sex, and body habitus.

Spiegel et al (26) demonstrated that sleep deprivation leads to impaired glucose tolerance in normal male subjects. Yaggi et al (27) further expanded these findings in a recent study, showing that diminished duration of sleep increases the risk of developing T2DM. Other studies have suggested that SA may have a causal role in the development of T2DM. Self-reported habitual snoring has been shown to be independently associated with impaired glucose tolerance and incident T2DM in population-based studies (28,29). Meslier et al (30) found a high rate of impaired glucose tolerance and T2DM in patients presenting to a sleep center for assessment of SA.

The most common and effective therapy for SA is nasal CPAP. This modality of treatment was first described in 1981 by Sullivan et al (31) and has become the standard of care for the treatment of SA. Recent work from Babu et al (32) showed that treatment of SA with CPAP in a population of patients with T2DM resulted in improvement of blood glucose levels after breakfast, lunch, and dinner. The magnitude of the glucose reductions was greater than one might see with any currently available orally administered agent to treat T2DM. This study also reported that those patients who used CPAP for at least 4 hours per night had a reduction in A1C levels that correlated with number of days of CPAP use. Other studies have also suggested that treating SA may diminish insulin resistance. With use of the euglycemic clamp method, Brooks et al (9) demonstrated an improvement in insulin sensitivity in patients with T2DM and SA who were treated with CPAP. Using the same methodology, Harsch et al showed an improvement in insulin sensitivity in patients with T2DM (33) and in a group with SA treated with CPAP (34).

Data for 51 of the 330 patients originally enrolled in our study were excluded from the analysis because the

ApneaLink device did not record a minimum of 2 hours of data. Inadequate recording time capture was related to various causes: (*1*) patients did not sleep a minimum of 4 hours during the night; (*2*) patients did not follow instructions for turning on the device; or (*3*) the nasal cannula used with the device became dislodged from the nares during the night. The clinical staff addressed these issues during the study by providing additional training and written instructions as well as by providing adhesive tape to secure the cannula during the night. Time and cost analysis for the device indicates that it is easy to use, taking comparable time to administer as other common tests currently performed in clinical practice.

Prevalence rates based on an AHI calculated from the PSG study confirmed our results, demonstrating findings comparable to those obtained from the ApneaLink (35). Because PSG is the standard for the diagnosis of SA, these results support the high prevalence of SA in the study population.

Our study population was drawn from consecutive patients referred to a diabetes practice and education center in La Jolla, California. The ethnic mix and socioeconomic status may not be representative of all parts of the United States.

CONCLUSION

This study shows that SA has a high prevalence in adults with T2DM and identifies several factors that may be associated with its presence in this population. Current guidelines for the management of patients with T2DM do not include evaluation for possible SA, despite clear evidence from many sources that SA can adversely affect many aspects of management and that treatment of SA can yield considerable improvements in glycemic control. SA can be usefully and easily assessed in an outpatient setting by using a portable device such as the ApneaLink. Because treatment of SA has the potential both to decrease blood pressure (36) and to improve glycemic control (32), and perhaps to aid in adherence to lifestyle efforts, it may be worthwhile to assess patients with T2DM for the presence of SA.

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DISCLOSURE

One author (E.C.) is employed by ResMed Corp, the manufacturer of the screening device used in this study. Because the objective of the study was to determine the prevalence of SA, not device performance, we do not believe that this interferes with the objectivity of our findings.

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