

ORIGINAL ARTICLE

SLEep among diabetic patients and their GlycaEmic control (SLEDGE): A pilot observational study*

Highlights

- The prevalence of excessive daytime sleepiness (EDS) among patients diagnosed with type 2 diabetes mellitus in an urban south Indian population is 17.5%.
- There is a significant positive correlation between EDS and glycemic control, as measured by HbA1c.

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Abstract

Background: Recent cohort studies have proven the association between sleep deprivation and adverse glycemic control (GC). The aim of this study was to assess the prevalence of excessive daytime sleepiness (EDS), a subjective measure of sleep deprivation, among type 2 diabetic mellitus (T2DM) patients and its association with GC.

Methods: This cross-sectional study was conducted between July 2015 and June 2016 in five diabetes clinics in the district of Erode, Tamil Nadu, India. An equal number of consenting patients with T2DM was recruited consecutively from each of the centers, and EDS was measured subjectively using the Epworth sleepiness scale (ESS), whereas GC was assessed using HbA1c levels.

Results: In all, 126 patients were screened and 102 were found eligible for the study. The prevalence of EDS was 17.5% (95% confidence interval 10.13–24.87). The association between ESS scores and HbA1c levels was analyzed using linear regression after adjusting for age, dietary intake, inflammatory markers (erythrocyte sedimentation rate), depression (Patient Health Questionnaire-9 score) and stress (Perceived Stress Scale score): for every unit increase in the ESS score, HbA1c increased by 0.143 g/dL (P < 0.001).

Conclusion: Subjective EDS was seen in approximately one-quarter of patients with diabetes in our population. There was a positive association between EDS and glycemic control. Screening of patients with diabetes for EDS should be part of routine diabetes management.

Keywords: excessive day time iness, sleep, diabetes mellitus, glycemic control, sleep, sleep deprivation.

Introduction

Type 2 diabetes mellitus (T2DM) is a global health problem, affecting over 422 million people in the year 2014, which equates to a prevalence of 8.5% among the global adult population.¹ The prevalence of T2DM has increased significantly since the 1980s, and it is estimated that nearly half the population with T2DM lives in South-East Asia and the Western Pacific.¹ According to the 2015 Diabetes Atlas released by the International Diabetes Foundation (IDF), India has the second-highest number of patients with T2DM in the world (69.1 million).² Lifestyle modifications, such as increasing physical activity and reducing calorie intake, have become the

mainstays of treatment for T2DM.³ More recently, epidemiological studies have demonstrated an association between sleep disturbance and adverse health outcomes, such as impaired glucose tolerance, obesity, hypertension, and other cardiovascular diseases (CVD); thus, improving sleep quality becomes another important lifestyle modification.⁴ Sleep has been defined as an important entity for general health and well being. Most sleep specialists advocate at least 7-8 h sleep per night.⁵ However, this varies considerably among individuals and it is difficult to define a cut-off point to define anyone as being sleep deprived. Therefore, sleep deprivation may be picked up by the presence of excessive daytime sleepiness (EDS), which may be the primary effect.⁶ However, sleep as a lifestyle modification is seldom emphasized to patients, and data on sleep deprivation among T2DM patients in south India is limited. Therefore, we performed a study among patients with T2DM visiting outpatient clinics in southern India to assess the prevalence of chronic sleep deprivation using EDS as a subjective measure and to investigate the association between sleep deprivation (EDS) and glycemic control.

Methods

The present cross-sectional study was conducted over 1 year between July 2015 and June 2016. All consenting patients with T2DM with a disease duration of >6 months were included in the study. All patients in the present study were residents of Erode City, Tamil Nadu, India. Cluster random sampling followed by systematic random sampling and stratification based on clusters was used to recruit study subjects. We planned to recruit an equal number of patients from five consenting diabetology clinics in Erode City that were chosen at random from the list of all registered multispecialty hospitals and diabetes clinics using a random number table. Based on a previous study with an estimated prevalence of sleep deprivation (p) of 34.2%, an absolute precision (d) of 10% and an alpha error of 5%, the sample size was calculated to be 90. To account for clustering, the calculated sample size was multiplied by the design effect (DE), where $DE = 1 + \rho$ (cluster size -1), where ρ is the correlation coefficient that is arbitrarily taken as 0.1. Considering that patients from one clinic may be a cluster because they would be treated by the same doctor or team of doctors with one institutional protocol, the cluster size was taken as 20, thus making the DE for the present study 1.19. The new sample size obtained after taking the DE into consideration was 105.

This study was approved by the Institutional Review Board (IRB), Christian Medical College, Vellore (IRB minutes no. 8995, 4 August 2014).

Every *n*th patient who was registered to meet the doctor for that day was included from each of the clinics until a sample size of 21 was reached, where n was a randomly chosen number between 2 and 5. Consecutive days were chosen until the sample size was reached in each clinic. Patients were excluded if they were seriously ill and could not answer our questions, had a psychiatric illness or dementia with loss of insight, were on regular medications that precipitated sedation as an adverse effect, were suffering from any acute illness that may affect sleep, were working night shift, and if they had a history of recent hospital admission in the previous 2 weeks. Written informed consent was obtained from the study participants and a semistructured pilot-tested standardized questionnaire was administered to them in the language of their choosing. This questionnaire had various components, including basic sociodemographic details, past medical history, Epworth Sleepiness Scale (ESS),⁸ and confounders (e.g. physical activity, calorie intake, stress, and depression). Information regarding past medical history and complications (both microvascular and macrovascular), as diagnosed by the treating physicians, was obtained from patients' medical records.

Diabetic nephropathy was defined as microalbuminuria >300 mg/day and diabetic retinopathy was diagnosed based on fundus findings. Peripheral vascular disease was defined as the absences of distal lower limb pulses or an ankle–brachial index <0.9. These diagnostic criteria were followed by all treating physicians. If any abnormality was detected, patients were referred back to their treating physician for further follow-up and confirmation of the comorbidity.

The ESS generated a numerical score from 0 to 24, wherein a score ≥ 10 was categorized as EDS.⁸ Physical activity levels were estimated using the International Physical Activity Questionnaire (IPAQ) short version.⁹ Examples of moderate and vigorous physical activities were explained using show cards published by the WHO (http://www.who.int/entity/chp/steps/GPAQ_GenericShowCards.pdf, accessed 25 February 2015) for the Global Physical Activity Questionnaire (GPAQ).¹⁰ Calorie intake was calculated with the help of a clinical nutritionist based on a 3-day dietary recall with at least 1 day being a weekend. Stress levels in patients were assessed using the Perceived Stress Scale (PSS),¹¹ and depression was assessed using the Patient Health Questionnaire-9 (PHQ-9).¹²

Different types of sleep disorders, including sleep disordered breathing, were screened for using a standardized questionnaire based on the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10). Restless leg syndrome (RLS) was screened for using the International Restless Legs Syndrome Study Group (IRLSSG) consensus diagnostic criteria for RLS/Willis–Ekbom disease (WED).¹³

The height and weight of patients were measured in order to calculate body mass index (BMI). Weight was measured using standardized weighing scales with an accuracy of 0.1 kg. Height was measured using regular measuring tapes with an accuracy of 0.1 cm. Finally, a fasting blood sample was collected from all patients and analyzed for HbA1c, lipid profile, and erythrocyte sedimentation rate (ESR).

Data were entered into Epi Info Version 7 (Centers of Disease Control and Prevention, Atlanta, GA, USA) and an analyses were performed using SPSS Statistics for Windows Version 20.0 (IBM Corp., Armonk, NY, USA). Demographic characteristics were summarized using descriptive statistics. The prevalence of excessive daytime sleepiness was reported as a proportion with 95% confidence intervals (CIs). The association between the ESS score and HbA1c was evaluated with multivariate analysis using a linear regression model. The confounders were evaluated with univariate analysis using simple linear regression, and those with P < 0.2 were used in multivariate analyses along with the ESS score. Statistical significance was set at two-tailed P < 0.05.

Results

Of the 126 patients screened, 102 were included in the present study. The main reasons for excluding patients were ongoing acute illness or infection (n = 12), being on medications that causes sedation (n = 7), dementia (n = 2), and hemolysis or clotting of blood samples (n = 3). The mean (\pm SD) age of the study participants was 56.88 ± 10.98 years. The sociodemographic characteristics of the study population are listed in Table 1. Nearly, half the study population was educated up to middle or high school and was employed. Almost threequarters of the patients were from the middle socioeconomic status (SES) class. The demographic features of those patients with uncontrolled diabetes (n = 68)whose HbA1c was ≥ 7 g/dL is also given in Table 1 and is representative of the entire sample. The mean $(\pm SD)$ HbA1c of the study population was 8.12 \pm 1.80 g/dL; in the uncontrolled and controlled T2DM groups, mean HbA1c was 8.99 ± 1.57 and 6.39 ± 0.51 g/dL, respectively. As indicated in Table 2, two-thirds of the study population had had T2DM for <10 years. Most

Sleep and glycemic control

Table 1 Sociodemographic characteristics of the study population

	Total population (n = 102)	Uncontrolled DM ($n = 68$)	
· · · · · ·	(
Age (years)			
30–44	13 (12.7)	12 (17.6)	
45–59	46 (45.1)	34 (50.0)	
≥ 60	43 (42.2)	22 (32.4)	
Sex			
Male	59 (57.8)	39 (57.4)	
Female	43 (42.2)	29 (42.6)	
Education			
Illiterate or primary school	24 (23.5)	16 (23.5)	
Middle or high school	50 (49.0)	31 (45.6)	
Diploma or degree	28 (27.5)	21 (30.9)	
Employment status			
Employed	51 (50.0)	36 (52.9)	
Unemployed	51 (50.0)	32 (47.1)	
SES			
Low	25 (24.5)	15 (22.1)	
Middle	76 (74.5)	52 (76.5)	
High	1 (1.0)	1 (1.5)	

Data are given as *n* (%).

DM, diabetes mellitus; SES, socioeconomic status based on Kuppuswamy's scale. $^{\rm 14}$

patients (84.3%) had no diabetes-related complications, whereas approximately 15% had symptoms of peripheral neuropathy. The prevalence of other complications, such as diabetic foot, CVD, and nephropathy, was low. The prevalence of hypertension was 58.8% and the mean (±SD) BMI was $21.64 \pm 3.35 \text{ kg/m}^2$.

The prevalence of EDS in the study population was 17.5% (95% CI 10.1–24.9). The mean (\pm SD) time in bed during the week was 7.32 \pm 0.91 h, compared with

Table 2 Duration of diabetes and complications in the study population (n = 102)

Duration of DM (years)	
< 10	66 (64.7)
10–19	27 (26.5)
20–28	9 (8.8)
Complications of DM*	
Peripheral neuropathy	15 (14.7)
Peripheral arterial disease	3 (2.9)
Myocardial infarction	2 (2.0)
Stroke or TIA	1 (1.0)
Diabetic nephropathy	3 (2.9)
None	86 (84.3)
Other comorbidities	
Hypertension	60 (58.8)
Overweight ⁺	34 (33.3)

Data are given as n (%).

*Patients could have more than one complication.

⁺Overweight was defined as a body mass index >25 kg/m².

DM, diabetes mellitus; TIA, transient ischemic attack.

Table 3 Pattern of sleep disorders

Sleep disorder	Total population (n = 102)	Uncontrolled DM (<i>n</i> = 68)
Snoring	23 (22.5)	17 (25.0)
Restless leg syndrome	17 (16.7)	11 (16.1)
Bad dreams	2 (2.0)	0 (0)
Difficulty maintaining sleep	1 (1.0)	1 (1.5)
Walk or talk in sleep	1 (1.0)	0 (0)
Difficulty initiating sleep	O (O)	0 (0)
None	60 (58.8)	50 (58.8)

Data are given as n (%).

DM, diabetes mellitus.

7.35 \pm 1.91 h on the weekend. Patients were screened for various sleep disorders as defined by the ICD-10. As indicated in Table 3, 22.5% (95% CI 14.9–31.9) complained of snoring. The next most common disorder was RLS (16.7%; 95% CI 10.0–25.3). Two patients reported bad dreams and one patient each reported talking while asleep and having difficulty staying asleep.

The results of analyses investigating the association between sleep and the glycemic index are summarized in Table 4. The ESS score and all hypothesized confounders, such as BMI, calorie intake, depression score (based on the PHQ-9), stress levels (based on the PSS), physical activity levels (low, moderate, or high based on IPAQ criteria), ESR as a marker of ongoing inflammation that may affect sleep, and male sex were included in the univariate analysis. Of these potential confounders, the ESS score, BMI, calorie intake, depression score, and decreasing age (P < 0.2 for all) were used in the multivariate analysis using a linear regression model. Except for BMI, the other confounders remained statistically significant. The ESS score was found to be significantly associated with the HbA1c values (β 0.143, 95% CI 0.065–0.220, P < 0.001). However, the univariate analysis itself did not reveal an association between ESS score and any of the serum lipid parameters, namely total cholesterol (P = 0.663), triglycerides (P = 0.239), low-density lipoprotein (P = 0.756), very low-density lipoprotein (P = 0.243), and high-density lipoprotein (P = 0.254).

Discussion

Erode City is the seventh largest city in Tamil Nadu (a state in south India); it is located on the banks of the Kaveri River and is known for its agricultural, food processing, and textile industries. According to the 2011 Census, Erode has an urban population of 521 891 and an adult sex ratio of 1008 women per 1000 men (national average 929 women per 1000 men).¹⁵ The main staple diet is rice, which has a high glycemic index, and most clinicians spend time trying to convince patients to replace rice with other food items, with much less time spent trying to educate patients on other lifestyle modifications, such as quality sleep. The prevalence of EDS in our study population was 17.5%. However, a similar study performed in Brazil in 2013 reported that the prevalence of EDS among T2DM patients was 55.5%,¹⁶ which is much higher than the results of the present study. This difference may be due to the fact that even in normal individuals, the prevalence of EDS may have been higher in the former study, similar to findings of a study from the US in 2009 that reported EDS among normal individuals was as high as 20%.17 This compares with a rate of 3% reported in India in 2003.¹⁸ This disparity could also be explained by the fact that prevalence of obstructive sleep apnea

Table 4 Association between sleep and glycemic control: results of univariate and multivariate analysis

Variable	Univariate analysis		Multivariate analysis	
	β	<i>P</i> -value	β (95% CI)	<i>P</i> -value
ESS score	0.170	< 0.001	0.143 (0.065, 0.220)	<0.001
BMI	0.001	0.049	-0.022 (-0.135, 0.091)	0.701
Calorie intake (per 100 cal)	0.067	0.028	0.051 (0.002, 0.107)	0.045
Depression	1.182	0.032	0.789 (0.362, 1.594)	0.026
Decreasing age	0.047	0.004	0.038 (0.073, 0.003)	0.035
Decreasing duration in bed				
During the week	0.192	0.978	Not included in analysis	
During the weekend	0.103	0.682	Not included in analysis	
ESR	0.006	0.404	Not included in analysis	
Physical activity*	0.029	0.211	Not included in analysis	
Stress	0.375	0.296	Not included in analysis	
Sex (male)	0.072	0.843	Not included in analysis	

*Categorized as low, moderate, or high.

BMI, body mass index; CI, confidence interval; ESR, erythrocyte sedimentation rate; ESS, Epworth sleepiness scale.

(OSA) in our population is probably much lower than that in the study population from Brazil,¹⁶ in which the prevalence of OSA was reported to be 40.9%. A history of snoring in just 22.5% of subjects, with only 33% of our study population being overweight, corroborates our hypothesis that OSA is comparatively lower among our study subjects. Finally, the possibility of crosscultural differences with regard to a few questions in the questionnaire cannot be ruled out. For example, not all Asian Indians drive vehicles, particularly women, which is one of the eight questions on the ESS.¹⁹ although this disparity with the West is closing fast over time. We also feel that when the study was performed would make a big difference in cultural perceptions of questions, because culture changes with time. Moreover, the prevalence of EDS assessed in the present study is approximately half the estimated prevalence that we considered when calculating the sample size. The study by Sridhar and Madhu⁷ was focused primarily on investigating the prevalence of sleep disturbances in T2DM and we hypothesized that a similar number of patients may be suffering from sleep deprivation because they had disturbed sleep. However, the vast difference between the actual and estimated prevalence may suggest that not all patients who have sleep disturbance are sleep deprived. This may be possible because some patients are able to compensate for their lost sleep by increasing their actual time in bed.²⁰ Because it is known that sleep deprivation worsens the glycemic index, it may be stated that methods to quantify the amount of sleep deprivation have to be improved, rather than focusing on a mere diagnosis of sleep disturbance in patients with T2DM. Therefore, appropriate interventions, such as lifestyle modification, should be advised to prevent sleep deprivation.

The present survey, performed to explore the number of patients at high risk of other sleep disorders, indicated that snoring was the most common disorder, probably affecting 23% of patients. These findings are in line with reports from other studies. A review article published in 2013 reported that the prevalence of OSA among T2DM patients could be anywhere between 20% and 30%.²¹ The interplay between OSA, T2DM, and obesity is complex. Reichmuth et al.²² concluded that sleep disordered breathing (SDB) led to weight gain and obesity, which, in turn, led to insulin resistance and T2DM. Conversely, 50% of obese patients have OSA and 86% of obese T2DM patients have OSA.²³ Diabetes is an independent risk factor for RLS.²⁴ Accordingly, RLS is the second most common sleep disorder, with 16.7% of patients in the present study having RLS. This finding is similar to the prevalence rate of 17.7% reported from Italy.²³

The multivariate regression test performed in order to evaluate the association between EDS and HbA1c revealed a statistically significant association. For every 1-unit increase in the ESS. HbA1c increased by 0.143 g/ dL (P < 0.001). The findings of a systematic review and meta-analysis published in 2016 that considered seven cohort studies and 29 649 patients, corroborate our finding that short sleep, compared with normal sleep, is associated with increasing HbA1c levels (weighted mean difference 0.23, 95% CI 0.10-0.36).25 Various factors have been proposed in the literature to explain the possible association between sleep and diabetes. As mentioned earlier, insulin resistance is one such factor. Sleep deprivation is believed to affect energy balance by increasing appetite, increasing the time taken to consume food, and reducing energy expenditure due to physical tiredness.²⁶ The Wisconsin Sleep Cohort study reported decreased leptin levels and increased ghrelin and leptin resistance secondary to nocturnal awakening.²⁷ Apart from direct effects on glucose metabolism, sleep deprivation may indirectly affect diabetes control through suboptimal diabetes self-care.²⁸

The present study has some limitations. First, the sample size is small and some of the tools used in the study were empirical. For example, dietary recall is considered less accurate than a prospective dietary record. Second, we used the short version of the IPAQ. Moreover, there are other devices, like calorimetry, that can measure energy expenditure prospectively.²⁹ Although we made an effort to search for an association between various lipid parameters and ESS, the analysis was not powered adequately because only a few patients were diagnosed with dyslipidemia based on our blood investigations. Conversely, the strengths of the study include the use of the HbA1c, which is reflective of diabetes control over the past 3 months. We also accounted for ongoing inflammation by using ESR as an objective measure. Furthermore, EDS was used rather than the mere prevalence of sleep disturbances to evaluate the association between sleep deprivation and diabetes control. Validated questionnaires were used to assess confounders such as depression, stress, EDS, and physical activity.

Conclusion

To the best of our knowledge, the present study is the first of its kind in India, particularly in a south Indian urban population. The study has also shown that there is a significant positive correlation between EDS, a subjective measure of sleep deprivation, and glycemic control. With nearly one-fifth of T2DM patients probably suffering from EDS, physicians who manage a patient with diabetes should be made aware of the merits of screening for sleep deprivation. The treating physician should also make it mandatory to include improving sleep quality as a lifestyle modification and educate their patients on good sleep hygiene. We recommend that sleep education and screening for sleep deprivation form part of routine diabetes management.

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Disclosure

The authors declare no conflicts of interest.

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