SLEEP QUALITY AND ITS ASSOCIATED FACTORS AMONG PATIENTS WITH DIABETES MELLITUS ATTENDING KLINIK RAWATAN KELUARGA

HOSPITAL UNIVERSITI SAINS MALAYSIA

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ABSTRAK

Kualiti tidur yang kurang baik adalah berkait rapat dengan penyakit kencing manis dan boleh menjejaskan kualiti hidup seseorang. Kajian ini bertujuan untuk menilai kualiti tidur pesakit kencing manis, faktor yang berkaitan, dan hubungannya dengan kualiti hidup seseorang . Kajian keratan rentas telah dijalankan di sebuah klinik penjagaan primer di sebuah hospital tertiari di pantai timur Malaysia. Kajian ini melibatkan 350 pesakit (175 lelaki dan 175 wanita). Data dikumpul menggunakan Indeks Kualiti Tidur Pittsburgh versi Bahasa Melayu (PSQI-M) dengan titik pemotongan markah >5 sebagai tidur yang tidak berkualiti, Skala Penderitaan Diabetes versi Bahasa Melayu (MDDS-17) dan Soal Selidik Kualiti Hidup berkaitan penyakit kencing manis versi Bahasa Melayu yang disemak semula (Rv-DQOL). Analisis statistik telah dijalankan menggunakan perisian SPSS versi 26.0. Umur median (IQR) pesakit ialah 62.0 (11.0) tahun, dan kurang kualiti tidur dilaporkan dalam 32% (95% selang keyakinan [CI] = 27.1, 36.9). Analisis regresi logistik mendedahkan bahawa kurang kualiti tidur dikaitkan dengan nokturia (odds ratio [OR] = 2.04; 95% CI = 1.24, 3.35), sindrom kaki tidak selesa (OR = 2.17; 95% CI = 1.32–3.56) dan beban emosi (OR = 2.37; 95% CI = 1.41–3.98). Walau bagaimanapun, kualiti tidur yang kurang tidak menjejaskan kualiti hidup.

Kata kunci: Diabetes jenis 2; kualiti tidur; tekanan kencing manis; kualiti hidup.

(207 patah perkataan)

ABSTRACT

Poor sleep is related to type 2 diabetes and adversely influences a person's quality of life. This study aimed to evaluate sleep quality in patients with type 2 diabetes (T2DM), its associated factors, and its relationship with quality of life. A cross-sectional study was conducted at a primary care clinic in a tertiary hospital on the east coast of Malaysia. This study included 350 participants (175 men and 175 women). Data were collected using the Malay version of the Pittsburgh Sleep Quality Index (PSQI-M) with a cut-off point of >5 as poor sleep, the Malay version of Diabetes Distress Scale (MDDS-17) and the revised Malay version of T2DM-related quality of life (Rv-DQOL). Statistical analysis was conducted using the SPSS software version 26.0. The respondents' median (interquartile range [IQR]) age was 62.0 (11.0) years, and poor sleep was reported in 32% (95% confidence interval [CI] = 27.1, 36.9) of the participants. Multivariate logistic regression analysis revealed that poor sleep quality was significantly associated with nocturia (odds ratio [OR] = 2.04; 95% CI = 1.24, 3.35), restless legs syndrome (OR = 2.17; 95% CI = 1.32–3.56) and emotional burden (OR = 2.37; 95% CI = 1.41–3.98). However, no statistically significant association was observed between sleep quality and quality of life among our participants.

Keywords: Type 2 diabetes; sleep quality; diabetes distress; quality of life.

(225 words)

CHAPTER 1

INTRODUCTION

Sleep is essential for the normal functioning of the body and mind. It is regulated by the circadian rhythm and the homeostatic pressure after being awake (Surani *et al.*, 2015). Poor or disrupted sleep has been linked to various diseases and ailments, poor performance, and workplace accidents and is reported to be associated with increased mortality (Najafian *et al.*, 2013). Sleep quality is a measure of a person's sensation of being healthy, active, and ready for a new day; adequate sleep is defined as a multidimensional construct rather than a single dimension such as duration (Tang *et al.*, 2017). Sleep quality is objectively assessed using instruments such as the actigraph, polysomnograph, and sleep electroencephalogram to determine sleep patterns (EEG) (Svetnik *et al.*, 2020). While subjectively, sleep quality can be measured by various validated questionnaires addressing multiple aspects of sleep construct such as latency and efficiency, and the most widely used tool to measure sleep quality in Pittsburgh Sleep Quality Index (PSQI) (Farah *et al.*, 2019).

According to growing evidence, sleep deprivation has been linked to an increased risk of T2DM; Sleep plays a vital role in modulating endocrine and metabolic function and sympathovagal balance; thus, sleep deprivation has negative impacts on these systems (Zhang *et al.*, 2019). People with T2DM, on the other hand, have more significant risk of having sleep disorders than the general population (Plantinga *et al.*, 2012). Sleep and wakefulness problems are common in people with T2DM due to physiological imbalances and co-morbid sleep disorders, resulting in poor sleep quality (Surani *et al.*, 2015). Obstructive sleep apnea (OSA) is a common

concomitant sleeping disorder in people with T2DM, especially obese people, and the severity of OSA is linked to poor glucose control (Lee *et al.*, 2017).

The prevalence of diabetes is rising worldwide. The latest edition of the International Diabetes Federation (IDF) Diabetes Atlas (2021) reported diabetes affects 537 million people globally. By 2030, this number is expected to rise to 643 million. Currently, 90 million individuals are living with diabetes in Southeast Asia, and the number is anticipated to climb by 63% to 130 million by 2045. IDF declared diabetes as one of the fastest-growing worldwide health emergencies of the twenty-first century (IDF, 2021). The complications are debilitating and have contributed to rising morbidity and mortality rates. T2DM is responsible for 1.6 million deaths worldwide, and other negative health outcomes include stroke, heart disease, hearing loss, blindness, hypertension, renal disease, and nerve damage (Samy *et al.*, 2021).

Physical inactivity and rising overweight and obesity were identified as contributing factors for the rising trend (WHO, 2016). According to data from previous National Health Morbidity Survey (NHMS) reports, there has been an increasing trend of overweight and obesity in Malaysia (Tee and Yap, 2017). In 2015, the combined prevalence of overweight and obesity was 47.7%, while the most recent report in 2019 stated that one in every two Malaysians is overweight or obese (Institute for Public Health Malaysia, 2020). This corresponded to an increase in the incidence of T2DM in Malaysia, where the prevalence among adults grew from 11.6% in 2006 to 17.5% in 2015. In 2019, one out of every five adults has T2DM, meaning that at least 20% (3.9 million) of the adult population is affected (Institute for Public Health Malaysia, 2020; Tee and Yap, 2017).

T2DM complications such as painful diabetic polyneuropathy, RLS, nocturia, and sleep-related breathing disturbance can impair sleep initiation and maintenance,

resulting in decreased sleep quality, daytime fatigue, and somnolence (Zhu *et al.*, 2018a). According to a recent meta-analysis, people with T2DM with poor sleep quality have greater HbA1c levels. There is a dose-response U-shape relationship between sleep duration and HbA1c; short and long sleep duration had detrimental effects on HbA1c compared to normal sleep duration. This demonstrated how critical adequate sleep is for T2DM patients (Lee *et al.*, 2017).

In the medical domain, quality of life denominates aspects of health from the patient's or subject's point of view; it is better expressed as "subjective health" or "functional status and well-being". It represents the effect of an illness as perceived by the patients and yields complementary information to medical or epidemiological data, often used as an outcome measurement (Chasens and Luyster, 2016). People with diabetes generally have worse quality of life than a healthy population but better than those with other serious chronic diseases. It is found that complications of diabetes are a significant disease-specific determinant of quality of life (de la Cruz *et al.*, 2020). Quality of life impairment among those with diabetes is multifactorial and is associated with the complexity of regimens, duration of disease, female gender, glycaemic control and poor knowledge (Cheah *et al.*, 2012). Sleep-related disturbances have been associated with a more inferior quality of life among patients with T2DM (Al-Taie *et al.*, 2020; Luyster and Dunbar-Jacob, 2011). Poor sleep quality as a result of pain, nocturia and depression may be a part of a vicious cycle in which disruption of sleep quality will contribute to neurohormonal changes, which in turn worsen the control of diabetes, making diabetes increasingly difficult to optimize (Skomro, 2008).

Primary care providers are frequently the first point of contact for T2DM patients. Education about the importance of sleep should begin as soon as a patient is diagnosed, focusing on disease understanding and treatment compliance. Thus, efforts

should be made to raise awareness about the relationship between sleep quality and illness. There is a paucity of reporting on sleep quality associates among patients with T2DM in Malaysia; hence, we conducted a cross-sectional study focused on sleep quality and quality of life.

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CHAPTER 2

OBJECTIVES

2.1 GENERAL OBJECTIVES

To determine the prevalence and identify the associated factors of poor sleep quality among people with T2DM in KRK, Hospital USM.

2.2 SPECIFIC OBJECTIVES

1. To determine the prevalence of poor sleep quality among patients with T2DM in KRK, Hospital USM.
2. To investigate whether socio-demographic factors, body mass index (BMI), duration of having T2DM, glycaemic control, insulin use, complications of diabetes, and diabetes-related distress are associated factors for poor sleep quality among patients with T2DM in KRK, Hospital USM.
3. To determine the association between sleep quality and quality of life among patients with T2DM attending KRK, Hospital USM.

2.3 RESEARCH HYPOTHESIS

1. Socio-demographic factors, body mass index (BMI), duration of having T2DM, glycaemic control, insulin use, complications of diabetes, and diabetes-related distress are significant associated factors for poor sleep quality among patients with T2DM in KRK, Hospital USM.

2. There is significant association between sleep quality and quality of life among patients with T2DM attending KRK, Hospital USM.

2.4 OPERATIVE DEFINITION

Sleep quality is defined as one's satisfaction of the sleep experience, integrating aspects of sleep initiation, sleep maintenance, sleep quantity, and refreshment upon awakening. In this study, sleep quality will be measured using the Pittsburgh Sleep Quality Index (PSQI), and scores of 5 and above will indicate poor quality of sleep (Buysse *et al.*, 1989).

CHAPTER 3

MANUSCRIPT

3.1 Introduction

The prevalence of type II diabetes (T2DM) is increasing worldwide. The latest edition of the International Diabetes Federation (IDF) Diabetes Atlas (2021) reported that T2DM affects 537 million people globally. It is expected that by 2030, this number will increase to 643 million. Currently, 90 million individuals are living with T2DM in Southeast Asia, and the number is anticipated to increase by 63% to 130 million by 2045. IDF declared T2DM as one of the fastest-growing worldwide health emergencies of the twenty-first century (IDF, 2021). The complications are debilitating and have contributed to rising morbidity and mortality rates. T2DM is responsible for 1.6 million deaths each year worldwide, and other negative health outcomes include stroke, heart disease, hearing loss, blindness, hypertension, renal disease and nerve damage (Samy *et al.*, 2021).

According to growing evidence, sleep deprivation has been linked to an increased risk of T2DM. Sleep plays a vital role in modulating endocrine, metabolic function and sympathovagal balance, and its deprivation has negative impacts on these systems (Zhang *et al.*, 2019). Studies done in Albania have shown poor sleep quality as a result of disruption in circadian rhythm, e.g., night shift work among nurses, causes a significant increase in HbA1c and body mass index (BMI) and influences certain gene expression in peripheral blood mononuclear cells that act as "peripheral clock genes". These changes typically manifest in people at risk of developing chronic metabolic diseases, especially T2DM (Rizza *et al.*, 2021; Zoto *et al.*, 2019).

On the other hand, people with T2DM have a more significant risk of having sleep disorders than the general population (Plantinga *et al.*, 2012). Sleep and

wakefulness problems are common in T2DM due to physiological imbalances and co-morbid sleep disorders, which results in poor sleep quality (Surani *et al.*, 2015). Obstructive sleep apnoea (OSA) is a common concomitant sleeping disorder in T2DM, especially among obese patients. The severity of OSA is linked to poor glucose control (Lee *et al.*, 2017).

T2DM complications, such as painful diabetic polyneuropathy, restless legs syndrome (RLS), nocturia and sleep-related breathing disturbance, can impair sleep initiation and maintenance, resulting in decreased sleep quality, daytime fatigue and somnolence (Zhu *et al.*, 2018). A recent meta-analysis revealed that T2DM patients with poor sleep quality have greater HbA1c levels. There is a dose–response U-shaped relationship between sleep duration and HbA1c; short and long sleep durations had detrimental effects on HbA1c compared with normal sleep duration (Lee *et al.*, 2017). This indicates how critical adequate sleep is for T2DM patients.

Sleep quality is a measure of a person's sensation of being healthy, active, and ready for a new day, whereas adequate sleep is defined as a multidimensional construct rather than a single dimension, such as duration (Tang *et al.*, 2017). Sleep quality is objectively evaluated using instruments such as the actigraph, polysomnograph and sleep electroencephalogram to determine sleep patterns (Svetnik *et al.*, 2020). Subjectively, sleep quality can be measured using various validated questionnaires addressing multiple aspects of sleep construct, such as latency and efficiency, and among the widely used tool to measure sleep quality is the Pittsburgh Sleep Quality Index (PSQI) (Farah *et al.*, 2019).

In the medical domain, quality of life is expressed as 'subjective health' or 'functional status and well-being'. It represents the effect of an illness as perceived by the subjects and is often used as an outcome measurement (Chasens and Luyster,

2016). People with T2DM generally have a worse quality of life compared with healthy people. It is found that complications of T2DM are a significant disease-specific determinant of quality of life (de la Cruz *et al.*, 2020). Sleep-related disturbances have been associated with a more inferior quality of life among T2DM patients (Al-Taie *et al.*, 2020; Luyster and Dunbar-Jacob, 2011).

Primary care providers are frequently the first point of contact for T2DM patients. Education on the importance of sleep should begin as soon as a patient is diagnosed, focusing on disease understanding and treatment compliance. Thus, efforts should be made to raise awareness of the relationship between sleep quality and illness. In Malaysia, there is a paucity of reporting on sleep quality associates among patients with T2DM. Thus, we conducted a cross-sectional study to look at the prevalence of poor sleep quality among patients with T2DM, its associated factors and its relationship with the quality of life.

3.2 Methods

3.2.1 Participants

This is a cross-sectional study conducted at Klinik Rawatan Keluarga, a primary care clinic at the Hospital Universiti Sains Malaysia, from November 2020 to January 2021. The participants were T2DM patients attending regular follow-up. Those aged more than 18 years old were included in this study. Those who suffered from acute complications of T2DM, such as hypoglycaemia, diabetic ketoacidosis and hyperglycaemic hyperosmolar coma, were excluded from this study. We also excluded those having other severe comorbidities, such as heart failure (uncontrolled with medications), kidney failure (stage 5 and end-stage renal failure) and respiratory

failure (such as co-morbid chronic obstructive pulmonary disease (COPD)), which would significantly affect the quality of life.

3.2.2 Measures

The sample size was calculated based on comparing two proportions for categorical variables using PS software version 3.1.2 with the power of study set at 80% and type I error set at 5%. Based on a study by Bani-Issa *et al.* (2018), the calculated sample size was 318, and after considering 10% non-response, the final sample size was 350 (Bani- issa *et al.*, 2018).

The clinical research tool used in this study consisted of a case report form. The case report form consisted of six sections. Section 1 included socio-demographic information. Section 2 provided details on DM among participants inclusive of the duration of diagnosis and treatment. The second part of Section 2 consists of self-reported symptoms of three T2DM complications, namely, nocturia, RLS and diabetic neuropathy. Section 3 provided information on the patient's height (m), weight (kg) and HbA1c (%).

Section 4 is the Malay version of the Pittsburgh Sleep Quality Index (PSQI-M). This self-administered questionnaire was originally developed by Buysse *et al*. in 1989, which was primarily intended to discriminate between poor and good sleepers over the past 1 month time (Buysse *et al.*, 1989). This was translated by Farah *et al.* (2019) with acceptable internal consistency values of 0.27 (test) and 0.68 (retest) (Farah *et al.*, 2019). The PSQI consists of 19 items; it is a self-report questionnaire that measures subjective sleep quality. These items are aggregated into seven components: (1) sleep quality (1 item), (2) sleep latency (2 items), (3) sleep duration (1 item), (4) sleep efficiency (3 items), (5) sleep disturbance (9 items), (6) sleep medication (1 item)

and (7) daily dysfunction (2 items). Each component has a score ranging from 0 to 3; the scores will be summed up to yield a PSQI global score ranging from 0 to 21. Respondents with a score of greater than 5 are 'poor sleepers', whereas those with a score of 5 or less are 'good sleepers' (Buysse *et al.*, 1989).

Section 5 consisted of the Malay version of T2DM distress scale (MDDS-17) translated by Chew *et al*. (2015) adapted from the original 17-item Diabetes Distress Scale by Polonsky *et al*. (2005), which assessed related problems and hassles concerning T2DM patients for the past 1 month using a Likert scale from 1 (not a problem) to 6 (a very serious problem). Scoring of this scale involves adding up the patient's responses according to specific items and dividing them by the number of items in that scale where a mean item score of ≥3 is considered a level of having distress deserving clinical attention; a score of <2.0 indicates little or no distress, whereas anything in between (score of 2.0 to 2.9) reflects moderate distress (Polonsky *et al.*, 2005). The original Diabetes Distress Scale has four items: physician-related distress (PD), regimen-related distress (RD), emotional burden (EB) and T2DM-related interpersonal distress (IPD). MDDS-17 has three items which are therapeutic support distress (TSD), made of combination of IPD and RD; EB, and RD. It has high internal consistency (Cronbach's $\alpha = 0.940$ and test–retest reliability value = 0.33) (Chew *et al.*, 2015*b*).

Section 6 utilised the revised Malay version of T2DM-related quality of life (Rv-DQOL) adapted from the Diabetes Quality of Life (DQOL) questionnaire. DQOL was intended to be used for evaluating the quality of life specifically related to T2DM and was made up of three major domains, namely, (i) Diabetes Life Satisfaction (QOL Satisfy), 18 items; (ii) Disease Impact Scale (QOL Impact), 27 items; and (iii) Disease-Related Worries Scale (QOL Worry), 14 items and one general question to reflect self-

rating of overall general health. All items in the QOL Satisfy domain are scored on a five-point scale, ranging from 1 (very satisfied) to 5 (very dissatisfied), whereas the items in the QOL Impact and QOL Worry are scored on a five-point scale, ranging from 1 (never) to 5 (all the time); the score was presented as the total of the items of each scale divided by the number of items. A higher average score indicates poorer QOL (Jacobson *et al.*, 1994). Recently, a new Malay version of the instrument was developed, keeping the three main domains of 'satisfaction', 'impact' and 'worry' with similar score scale. Each domain's redundant questions were removed, leaving the newly revised DQOL (Rv-DQOL) with a total of 13 questions. Cronbach's α values for each domain ranged from 0.75 to 0.93, indicating good internal consistency, and it was validated for use among adult T2DM patients in Malaysia. This tool does not have an objective cut-off point to differentiate between good and poor quality of life; a higher score indicates a lower quality of life (Bujang *et al.*, 2018). All the three translated questionnaires used had permission from the authors who modified them.

3.3 Statistical analysis

Data were analysed using the SPSS software version 26.0 (SPSS Inc., Chicago, IL, USA). Numerical data were expressed in median and interquartile range (IQR). The dependent variable was sleep quality. Univariate logistic regression analysis was conducted to identify significant factors affecting sleep quality. Any factors with *P* values <0.25 were subjected to multiple logistic regression analyses. A confirmatory analysis to determine the association between sleep quality and quality of life was measured using simple linear regression, in which the dependent variable is quality of

life, whereas the independent variable is sleep quality. For all conducted statistical analyses, the significant value was set to $\alpha = 0.05$.

3.4 Results

3.4.1 Socio-demographic and medical characteristics among participants

A total of 350 patients with T2DM participated in this study with a response rate of 100%. The median (IQR) age of the respondents was 62.0 (11.0) years. Their age ranged from 28 to 83 years old. The respondents consisted of an equal number of men and women. The majority are Malays, 317 (90.6%) and married (85.4%). One-third of the participants, 32% (95% CI = 27.1, 36.9), had poor sleep quality represented by 112 participants. Table 1 presents the detailed socio-demographic information of the participants.

Table 1 Socio-demographic characteristics of participants (N = 350)

Variables	**Total N (%)**	**Poor Sleep n (%)**	**Good Sleep n (%)**
SOCIODEMOGRAPHIC			
Age (years old) [a]	62.00 (11.00)	61.00 (12.00)	62.00 (10.00)
Sex			
Female	175 (50.0)	57 (50.9)	118 (49.6)
Male	175 (50.0)	55 (49.1)	120 (50.4)
Ethnicity			
Malays	317 (90.6)	100 (89.3)	217 (91.2)
Non-Malays	33 (9.4)	12 (10.7)	21 (8.8)
Marital Status			
Married	299 (85.4)	98 (87.5)	201 (84.5)

Others	51 (14.6)	14 (12.5)	37 (15.5)
Education			
Less than Tertiary	251 (71.7)	81 (72.3)	170 (71.4)
Tertiary Onwards	99 (28.3)	31 (27.7)	68 (28.6)
Working Status			
Working	121 (34.6)	41 (36.6)	80 (33.6)
Not Working	229 (65.4)	71 (63.4)	158 (66.4)

[a] Median (IQR)

The median and IQR for HbA1c (%) and body mass index (BMI) in kg/m^2 were 8.20 (3.20) and 28.05 (6.10), respectively. Table 2 presents other medical characteristics of the participants.

Table 2 Medical characteristics of participants (N = 350)

Variables	**Total N (%)**	**Poor Sleep n (%)**	**Good Sleep n (%)**
MEDICAL CHARACTERISTICS			
Duration of Diagnosis as DM			
Less than 10 years	178 (50.9)	59 (52.7)	119 (50.0)
10 years and more	172 (49.1)	53 (47.3)	119 (50.0)
Insulin Therapy			
Yes	160 (45.7)	55 (49.1)	105 (44.1)
No	190 (54.3)	57 (50.9)	133 (55.9)
Painful Neuropathy			
Yes	157 (44.9)	56 (50.0)	101 (42.4)
No	193 (55.1)	56 (50.0)	137 (57.6)

Nocturia			
Yes	222 (63.4)	83 (74.1)	139 (58.4)
No	128 (36.6)	29 (25.9)	99 (41.6)
Restless Legs Syndrome			
Yes	91 (26.0)	41 (36.6)	50 (21)
No	259 (74.0)	71 (63.4)	188 (79)
HbA1C [a]	8.20 (3.20)	8.00 (3.30)	8.20 (3.20)
Less than 7%	258 (73.7)	82 (73.2)	176 (73.9)
7% and more	92 (26.3)	30 (26.8)	62 (26.1)
BMI [a]	28.05 (6.10)	28.48 (5.50)	28.00 (5.90)
Overweight	321 (91.7)	106 (94.6)	215 (90.3)
Non-Overweight	29 (8.3)	6 (5.4)	23 (9.7)
DIABETES-RELATED DISTRESS			
Emotional Burden			
No	272 (77.7)	75 (67.0)	197 (82.8)
Yes	78 (22.3)	37 (33.0)	41 (17.2)
Physician related Distress			
No	334 (95.4)	106 (94.6)	228 (95.8)
Yes	16 (4.6)	6 (5.4)	10 (4.2)
Therapeutic Support Distress			
No	319 (91.1)	98 (87.5)	221 (92.9)
Yes	31 (8.9)	14 (12.5)	17 (7.1)

[a] Median (IQR)

3.4.2 Associated factors for poor sleep quality among patients with T2DM

Simple logistic regression revealed that T2DM complications, namely, nocturia and RLS, together with the EB component of T2DM-related distress, are significant associated factors contributing to poor sleep quality among the participants. These results are presented in Table 3.

Table 3 Associated factors for poor sleep quality among patients with T2DM using simple logistic regression.

Variables	**B**	**Crude OR[a] (95% CI)[b]**	**Wald Stat.[c] (df)**	**p-value**
SOCIODEMOGRAPHIC				
Age	0.00	1.00 (0.98,1.03)	0.00 (1)	0.978
Sex				
Female		1.00		
Male	0.05	1.05 (0.67,1.65)	0.05 (1)	0.819
Ethnicity				
Non-Malays		1.00		
Malays	-0.22	0.81 (0.38,1.70)	0.32 (1)	0.573
Marital Status				
Unmarried		1.00		
Married	0.25	1.29 (0.67,2.50)	0.57 (1)	0.452
Education				
Less than Tertiary		1.00		
Tertiary Onwards	-0.04	1.05 (0.63,1.72)	0.03 (1)	0.863
Working Status				
Working		1.00		

Not Working	-0.13	1.14 (0.71,1.82)	0.30 (1)	0.583
MEDICAL CHARACTERISTICS				
Duration of Diagnosis as DM				
Less than 10 years		1.00		
10 years and more	-0.11	0.90 (0.57,1.41)	0.219 (1)	0.640
Insulin Therapy				
No		1.00		
Yes	0.20	1.22 (0.78,1.92)	0.76 (1)	0.382
Painful Neuropathy				
No		1.00		
Yes	0.31	1.36 (0.86,2.13)	1.76 (1)	0.185
Nocturia				
No		1.00		
Yes	0.71	2.04 (1.24,3.35)	7.95 (1)	0.005*
Restless Legs Syndrome				
No		1.00		
Yes	0.78	2.17 (1.32,3.56)	9.42 (1)	0.002*
HbA1C (%)				
<7 (controlled)		1.00		
≥7 (uncontrolled)	-0.04	0.96 (0.58,1.60)	0.02 (1)	0.884
BMI (kg/m^2)				
<23 (non-overweight)		1.00		
≥23 (overweight)	0.64	1.89 (0.75,4.78)	1.81 (1)	0.179

DIABETES-RELATED DISTRESS				
Emotional Burden				
No		1.00		
Yes	0.86	2.37 (1.41,3.98)	10.66 (1)	0.001*
Physician Related Distress				
No		1.00		
Yes	0.26	1.29 (0.46,3.64)	0.23 (1)	0.630
Therapeutic Support Distress				
No		1.00		
Yes	0.62	1.86 (0.88,3.92)	2.64 (1)	0.104

[a] Crude Odds Ratio [b] Confidence Interval [c] Wald statistic * p-value ≤ 0.05

Table 4 Associated factors for poor sleep quality among patients with T2DM using multiple logistic regression

Variable	**B**	**Adjusted OR[a] (95% CI)[b]**	**Wald Statistic[c] (df)**	**p-value**
Nocturia				
No		1.00		
Yes	0.66	1.93 (1.16,3.20)	6.51 (1)	0.011*
Restless Legs Syndrome				
No		1.00		
Yes	0.57	1.78 (1.06,2.99)	4.67 (1)	0.031*
Emotional Burden				

No		1.00		
Yes	0.70	2.02 (1.17,3.48)	6.448 (1)	0.011*

[a] Adjusted odds ratio
[b] Confidence interval
[c] Wald statistic
* p-value ≤ 0.005
Note. No significant interaction; no multicollinearity problem; model assumptions met.

According to the multiple logistic regression analysis shown in Table 4, participants with nocturia, RLS and EB have a significant relationship with poor sleep quality. When controlling for RLS and EB, T2DM patients with nocturia had 1.93 times the odds (Adj. OR = 1.93; 95% CI = 1.16, 3.20; *P* = 0.011) of having poor sleep quality than T2DM patients without nocturia. When nocturia and EB were controlled, participants with RLS had 78% more chances (Adj. OR = 1.78; 95% CI = 1.06, 2.99; *P* = 0.031) of having poor sleep quality. When nocturia and RLS were controlled, those who were emotionally burdened had two times higher chance of having poor sleep quality than those who were not emotionally burdened (Adj. OR = 2.02; 95% CI = 1.17, 3.48; *P* = 0.011).

3.4.3 Association between sleep quality and quality of life among patients with T2DM

Based on simple linear regression model, an increase in 1 in the PSQI-M score would increase the score of T2DM Rv-DQOL by 0.37, but there was no statistically significant relationship between the two (*P* = 0.234, 95% CI −0.24, 0.98). Furthermore, the r^2 value was very low (0.004), indicating that sleep quality score (PSQI-M) accounts for only 0.4% of the variation in the quality of life (T2DM RV-DQOL). Table 5 presents the results that have been explained.

Table 5 Association between sleep quality and quality of life using simple linear regression

Variable	β	95%CI[a]	*p*-value	r^2
PSQI Score	0.37	-0.24, 0.98	0.234	0.004

[a] Confidence Interval
constant = 35.766

3.5 Discussion

3.5.1 Prevalence of poor sleep quality

This study found that the prevalence of poor sleep quality based on the PSQI-M score among T2DM patients attending primary health clinics is 32%. This finding is similar to a study conducted in Japan among similar subjects, which found 30.6% of the participants (Otaka *et al.*, 2019). Data from a large cohort population study in the United Kingdom indicated that 28% of the T2DM patients studied experienced sleep disturbances (Von Schantz *et al.*, 2021). A study conducted by Lou *et al.* (2015) in China involving 944 patients with T2DM demonstrated that 33.6% of them were poor sleepers (Lou *et al.*, 2015). These studies all showed similar results of prevalence: roughly one-third of the T2DM study participants have poor sleep quality. This is supported by a recent meta-analysis, which found that the pooled prevalence of insomnia among T2DM patients was 39% (Koopman *et al.*, 2020). Nevertheless, the prevalence of poor sleep quality within a control group in a study by Narisawa *et. al.* (2017) was reported to be 38.4% (Narisawa *et al.*, 2017). In a large general population study in China by Tang *et. al.* (2017), the overall prevalence of insomnia was reported to be 26.6% (Tang *et al.*, 2017). Poor sleep quality is as common among those without T2DM, signifying the multifactorial attributes of the problem. Inadequate sleep or poor sleep quality has been related to adverse health outcomes like elevated systemic markers of inflammation, high blood pressure, impaired glucose tolerance and T2DM

development (Cappuccio *et al.*, 2010; LeBlanc *et al.*, 2018; Najafian *et al.*, 2013; Okamoto *et al.*, 2017). This relationship helps explain the plethora of sleeping problems among T2DM patients.

3.5.2 Associated factors for poor sleep quality

This study discovered three factors to be significantly associated with poor sleep quality, namely, nocturia, RLS and the EB. A study conducted among female T2DM patients in Taiwan obtained similar finding where nocturia was found to be significantly correlated with sleep quality (Pearson's correlations showing Chinese PQSI score r = 0.28, $P < 0.01$) (Chang *et al.*, 2017). Another study conducted by researchers from a neighbouring country, Singapore, found a significant association between nocturia and poor sleep quality (adjusted prevalence rate ratio of 1.54, 95% CI 1.06–2.26) among the elderly with T2DM, hyperlipidaemia and hypertension (Chiang *et al.*, 2018). On the other hand, a study by Nasseri *et al*. (2015) found that nocturia did not significantly cause poor sleep quality and concluded that although T2DM is responsible for disrupting sleep, it is unrelated to chronic complications such as nocturia and painful neuropathy (Nasseri *et al.*, 2015). Interestingly, according to a study conducted in Brazil, having nocturia increased the chances of falling into the 'oversleeping' (>8 h) category (Martorina and Tavares, 2019). A logical explanation from our finding is that getting up from sleep to urinate at least once potentially causes cumulative sleep deprivation, more so if patients had to wake up more than once. In addition, waking up in the middle of a deep sleep may negatively affect sleep quality (Rosen *et al.*, 2013).

Numerous studies highlighted that RLS is more common in patients with T2DM compared with the general population, with a prevalence of 8%–45% (Cho *et*

al., 2013; Harashima *et al.*, 2016; Modarresnia *et al.*, 2018; Schipper *et al.*, 2021; Zobeiri and Shokoohi, 2014). In those without T2DM, the prevalence of having RLS is lower (10-12%) as depicted in studies by Winter *et. al.* (2012) and Zobeiri *et. al.* (2014) (Winter *et al.*, 2012; Zobeiri and Shokoohi, 2014).In our study, 26% of the participants had symptoms of RLS, and they were significantly associated with poor sleep quality. This is supported by a study from India, where T2DM patients with RLS had a significant delay in sleep onset and a higher PSQI score (Pinheiro *et al.*, 2020). Another study in Iran found that T2DM patients who had RLS were nearly three times more likely to have poor sleep quality (Modarresnia *et al.*, 2018). RLS is well understood to be a complicated and distressing condition. It disrupts the initiation and subsequent maintenance of sleep because the unpleasant sensation, if present, is more prominent during rest or when lying down, particularly at night. To break free from this, the sufferer must move his/her lower limbs by shaking, walking or stretching. An interventional study from Japan found a significant improvement in RLS symptoms and sleep quality after 3 months of treatment with the dopamine agonist pramipexole (Harashima *et al.*, 2016). Given the predominance of RLS in T2DM patients and the fact that it is treatable, it is critical to recognise and actively seek it out to improve sleep quality and overall outcomes.

Our study also found that emotionally burdened patients were significantly associated with poor sleep quality. Several local studies used similar tool (MDDS-17) to investigate the prevalence and associated factors of T2DM-related distress; however, to the best of our knowledge, none studied its dependency on sleep quality (Alvani *et al.*, 2015; Chew *et al.*, 2015a; Chew *et al.*, 2016; Devarajooh and Chinna, 2017). A study conducted in Iran demonstrated that psychological distress is an independent risk factor for poor sleep quality among T2DM patients (Shamshirgaran

et al., 2017). Two studies from China with similar backgrounds investigated the reverse relationship and revealed that sleeping time is significantly related to both the overall T2DM distress score and its EB component. However, they used total sleep time in a day as a sleep quality measure rather than the PSQI (Bao *et al.*, 2018; Zhou *et al.*, 2017). Having disease-related psychological distress and emotional disturbance affect sleep because of interruption in complex neurohormonal physiology could be possible explanations for our findings. Cortisol is released in response to stress, causing agitation and arousal and thus disrupting the sleep–wake cycle, which is controlled by the circadian rhythm.

3.5.3 Association between sleep quality and quality of life

Using simple linear regression analysis, we discovered a weak and insignificant link between sleep quality and quality of life. Because the r^2 value was so low (0.004), it meant that there were many other factors influencing the variation in the quality-of-life score aside from sleep. The tool we used in this study is relatively new (released in 2018) and has seen limited research use. This tool was used in two local studies that investigated the link between medication adherence and quality of life (Azmi *et al.*, 2021; Mohd Shaiful Ehsan *et al.*, 2020). To the best of our knowledge, this is the first study investigating the relationship between sleep quality and quality of life using the aforementioned tool.

A few local studies investigated the factors that influence the quality of life among T2DM patients using various tools, such as WHO Quality of Life–Brief (WHOQOL-BREF), Short Form Survey 36 (SF-36) and Malay version of DQOL (Cheah *et al.*, 2012; Chew *et al.*, 2015a; Kueh *et al.*, 2017). A study in the United Arab Emirates found a high independent association between sleep quality and quality of