

SCIENTIFIC INVESTIGATIONS

Restless Legs Syndrome in Iranian People With Type 2 Diabetes Mellitus: The Role in Quality of Life and Quality of Sleep

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Study Objectives: To investigate the prevalence of restless legs syndrome (RLS) in patients with type 2 diabetes mellitus (T2DM) and explore its role in quality of life (QoL) and quality of sleep of these patients.

Methods: This is a cross-sectional study performed on 210 Iranian people with T2DM. The diagnosis of RLS was established based on the essential diagnostic criteria for RLS recommended by the National Institutes of Health. Sleep quality and QoL were assessed in all participants using Pittsburgh Sleep Quality Index and EuroQol five-dimension questionnaire, respectively. Regression models were used for final analysis of data.

Results: The prevalence of RLS was 19.5%; of whom 38.1% had poor quality of sleep. Male sex, being single, body mass index (BMI), and RLS were associated with poor quality of sleep. Patients with RLS were almost three times as likely as the patients without RLS to have poor sleep quality. Moreover, being female, BMI value, level of glycosylated hemoglobine (HbA1C), and RLS were associated with lower QoL. RLS lowers the score of QoL even more than BMI and HbA1C. In addition, the QoL and sleep quality of this population of patients with diabetes have not been affected by the severity of RLS as well as presence or absence of neuropathy.

Conclusions: RLS has an independent and significant role in sleep quality and QoL in the patients with diabetes. Neuropathy with RLS does not confer any additive burden on QoL and sleep quality of this population of patients with diabetes.

Keywords: quality of life, quality of sleep, restless legs syndrome, type 2 diabetes

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Restless legs syndrome (RLS) is a common disorder seen in patients with diabetes. This study aimed to determine the prevalence and severity of RLS in a population of patients with diabetes and identify its role in sleep quality and quality of life of these patients.

Study Impact: Having identified the effect of RLS on quality of life and sleep quality of patients with diabetes, we should pay more attention to this issue when determining their treatment plan.

INTRODUCTION

Restless legs syndrome (RLS) is a circadian sensorimotor disorder, manifested by an urge to move the legs, and usually associated with uncomfortable sensation in the legs.¹ The urge to move or unpleasant sensation arise or worsen at nights and during the episodes of inactivity, and are partially or totally relieved by movement.¹ RLS is often familial or idiopathic² but may be associated with iron deficiency anemia,³ renal failure,⁴ thyroid disorders,⁵ neuropathy of different causes,⁶ pregnancy,⁷ and type 2 diabetes mellitus (T2DM).⁸

RLS imposes a significant burden not only on quality of sleep and quality of life (QoL)^{2,9} but also on physical health¹⁰ and health-related costs.⁹ Sleep-related symptoms are the most common and most destructive symptoms experienced by patients with RLS.¹¹ Sleep is both quantitatively and qualitatively impaired by RLS.¹¹ Furthermore, sleep disturbance is responsible for a large proportion of burden of RLS on QoL.⁹ The adverse effects of RLS on QoL are more severe than those

imposed by hypertension, recent myocardial infarction, congestive heart failure, angina, diabetes mellitus, and osteoarthritis.¹² In addition, sleep disturbance, a cardinal feature of RLS, has been shown to be a risk factor for impaired glucose tolerance,¹³ insulin resistance, and T2DM.¹⁴

However, diabetes, a lifelong disease of increasing prevalence, is considerably associated with sleep disturbance and subsequently poor glycemic control through different mechanisms.¹⁵ RLS, a common comorbidity in patients with diabetes,^{8,16} can also adversely affect the quality of sleep of these patients.^{16,17} However, this condition is frequently underdiagnosed.⁹ Although identification of sleep abnormalities and their effects on QoL in patients with diabetes is the subject of many studies, only a few studies looked into RLS and its effect on both QoL and quality of sleep of this population. Further understanding of the link between diabetes and RLS is an important part of the efforts done to prevent and treat diabetes complications. Thus, in this study, we investigated the prevalence and severity of RLS in an Iranian population of patients

with T2DM and determined the role of RLS in QoL and quality of sleep in these patients to highlight the burden of this neglected but severely disabling disorder.

METHODS

This is a cross-sectional study on patients with T2DM, done at a tertiary care center, in Iran, Tehran, in 2016. Patients with T2DM, according American Diabetic Association criteria,¹⁸ were selected using the convenience sampling method. The sample size including 210 participants was determined applying the observational study formula.¹⁶ Exclusion criteria were any known chronic kidney disease (CKD), severe heart disease, liver disease, active thyroid disorder, obstructive sleep apnea (OSA), depression, a history of trauma or hospital admission during the past 3 months, diabetic duration of less than 3 months, and age younger than 30 years or older than 70 years. An informed written consent was obtained from all the subjects eligible for including in the study.

The diagnosis of RLS was established by a physician based on the essential diagnostic criteria for RLS recommended by the National Institutes of Health,¹ utilizing the validated Persian language version. The criterion excluding RLS mimics is not included in the National Institutes of Health criteria; however, we excluded RLS mimics (namely, myalgia, venous stenosis, leg edema, leg cramp, positional discomfort, habitual foot tapping) by an exact physical examination and mimics-related questions.¹ Diabetic neuropathy was documented by nerve conduction study. Severity of RLS was evaluated with the International RLS Study Group Rating Scale.¹⁹ RLS severity was classified to mild (0–10), moderate (11–20), severe (21–30), and very severe (31–40) according to total International RLS Study Group Rating Scale scores.

Sleep quality was measured in all participants using Pittsburgh Sleep Quality Index (PSQI).^{20,21} Sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep medications, and daytime dysfunction were evaluated subjectively through 19 self-rating items. Each of the seven factors was scored 0 to 3. PSQI total score ranged from 0 to 21; the higher PSQI global score indicates the poorer quality of sleep. PSQI global score higher than 5 has been found to have a sensitivity of 98.7% and specificity of 84.4% in differentiating good sleepers from poor sleepers.²²

QoL was assessed in all participants using EuroQol five-dimension questionnaire (EQ-5D-3L), a standardized tool for measuring general health status.²³ This questionnaire consists of two components, a health state description part and a visual analog scale (VAS).²⁴ Five dimensions of health status, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, are measured in the description part. The respondents self-rate the level of severity of each dimension using a three-level scale. The VAS indicates health status on the day of interview on a 20-cm vertical scale with end points of 0 and 100.²⁴ In the EQ-5D-3L, the respondent has to draw a line from the box on the questionnaire to the imagined scale.

Weight, height, and blood pressure were measured; another questionnaire including demographic information (age, sex,

occupation, marital status, and smoking status), diabetes-related variables (including duration of diabetes and type of treatment), as well as physician-diagnosed comorbidities (ie, hypertension, hyperlipidemia, thyroid disorders, anemia, CKD, severe heart disease, liver disease, OSA, depression, and hospital admission during the past 3 months) were completed by the participants. In addition, in the same session a blood sample was obtained for laboratory testing of fasting blood sugar, glycated hemoglobin (HbA1C), total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglyceride.

All the questionnaires were completed via a face-to-face interview between trained physicians and participants. The questions that arose during the interview were explained and clarified by the investigators. Moreover, if the participants were unable to complete the questionnaires, the physicians asked them the questions item-by-item orally and recorded the answers truthfully.

Statistical Analysis

Data are presented as mean \pm standard deviation for continuous variables with normal distribution or median and interquartile range for non-normally distributed variables. Categorical data are presented as frequency and percentage. Analysis of variance, Mann-Whitney *U* test, Kruskal-Wallis test, and χ^2 test were used for comparison of variables between groups. Correlations were evaluated using the Spearman correlation coefficient. After performing the univariate analysis, the variables with $P < .2$ were included in multivariate analysis. For multivariate analysis, binary logistic regression model and linear regression analysis were used. A value of $P < .05$ was considered statistically significant. The Statistical Package for Social Sciences (SPSS) version 24 (SPSS Inc., Chicago, Illinois, United States) was used for statistical analysis.

RESULTS

Baseline characteristics of all participants are shown in **Table 1**. Two hundred ten patients with T2DM were included in the study. The mean age of participants was 54.89 ± 7.81 years and mean diabetic duration was 7.8 ± 4.89 years. The prevalence of RLS was 19.5% ($n = 41$) in this population of patients with diabetes, of whom 21 (51.2%) had evidence of neuropathy whereas 20 (48.8%) had no evidence of neuropathy in nerve conduction tests. Based on the International RLS Study Group Rating Scale, 29.3%, 51.2%, 14.6%, and 4.9% of the patients were affected by mild, moderate, severe, and very severe forms of RLS, respectively.

There were 38.1% of all participants and 56.1% of the participants with RLS who had poor quality of sleep. Binary logistic regression model showed poor quality of sleep is associated with male sex (odds ratio [OR] 3.17; 95% CI 1.60–6.29; $P = .001$), being single (OR 3.60; 95% CI 1.04–12.36; $P = .04$), higher body mass index (BMI) level (OR 0.93; 95% CI 0.87–0.98; $P = .014$), and the presence of RLS (OR 2.79; 95% CI 1.30–5.99; $P = .008$), **Table 2**. The effect of RLS on sleep quality was independent of the presence of neuropathy.

Table 1—Baseline characteristics of the participants.

Age (years)		54.89 ± 7.81
Diabetic duration (years)		7.8 ± 4.89
SBP (mmHg)		128.65 ± 19.22
DBP (mmHg)		79.83 ± 9.47
FBS (mg/dL)		154.9 ± 66.2
HbA1C (%)		7.84 ± 1.92
TG (mg/dL)		161.74 ± 96.10
Cholesterol (mg/dL)		166.14 ± 43.08
LDL (mg/dL)		92.37 ± 31.55
HDL (mg/dL)		44.27 ± 11.51
QoL (score)		0.82 ± 0.17
VAS (score)		66.24 ± 18.89
Sex	Male	83 (39.5)
	Female	127 (60.5)
Marital status	Single	26 (12.4)
	Married	184 (87.6)
Smoking status	Yes	15 (7.1)
	No	195 (92.9)
Insulin use	Yes	71 (33.8)
	No	139 (66.2)
RLS	Yes	41 (19.5)
	No	169 (80.5)
RLS	With neuropathy	21 (51.2)
	Without neuropathy	20 (48.8)
PSQI score	≤ 5	130 (61.9)
	> 5	80 (38.1)

Data are presented as mean ± standard deviation or n (%). DBP = diastolic blood pressure, FBS = fasting blood sugar, HbA1C = glycosylated hemoglobin, HDL = high density lipoprotein, LDL = low-density lipoprotein, PSQI = Pittsburgh Sleep Quality Index, QoL = quality of life, RLS = restless legs syndrome, SBP = systolic blood pressure, TG = triglyceride, VAS = visual analog scale.

Linear regression analysis for identifying the associated factors of poor QoL demonstrated the significant effect of sex (male) (coefficient 1.50; $P = .001$), BMI (coefficient -0.008 ; $P < .001$), HbA1C (coefficient -0.015 ; $P = .02$), and RLS (coefficient -0.08 ; $P = .007$) on QoL (**Table 3**). In the VAS part of the questionnaire, female sex (coefficient -6.04 ; $P = .03$), duration of diabetes (coefficient -0.62 ; $P = .02$), BMI (coefficient -0.5 ; $P = .02$), and being a smoker (coefficient -16.17 ; $P = .003$) all were associated with an inverse effect on QoL (**Table 4**). Furthermore, patients with poor quality of sleep showed significantly lower scores in both parts of the EQ-5D-3L questionnaire compared with patients with good quality of sleep (0.80 versus 0.84, $P < .001$, in the health state description part; and 60 versus 70, $P < .001$, in the VAS part). Finally, our data showed that the

Table 2—Binary logistic regression analysis of factors influencing quality of sleep.

Variable	OR (95% CI)	P
Male	3.176 (1.602–6.293)	.001
Single	3.600 (1.049–12.369)	.042
BMI	0.930 (0.878–0.986)	.014
TG	0.998 (0.995–1.001)	.205
RLS	2.793 (1.301–5.998)	.008

Multivariate logistic regression analysis, dependent variable is poor quality of sleep (PSQI > 5) and covariates are: sex, marital status, BMI, TG, and RLS. BMI = body mass index, CI = confidence interval, OR = odds ratio, PSQI = Pittsburgh Sleep Quality Index, RLS = restless legs syndrome, TG = triglyceride.

Table 3—Linear regression analysis of factors influencing QoL.

Variable	Coefficient (SE)	P
Male	1.508 (0.128)	.001
Age (years)	-0.083 (0.025)	.051
BMI (kg/m ²)	-0.008 (0.002)	< .001
HbA1C (%)	-0.015 (0.006)	.021
TG (mg/dL)	-0.0001 (0.0001)	.345
RLS	-0.082 (0.03)	.007
Insulin use	-0.28 (0.028)	.309

Dependent variable is QoL and covariates are: sex, age, BMI, HbA1C, TG, RLS, and insulin use. BMI = body mass index, HbA1C = glycosylated hemoglobin, QoL = quality of life, RLS = restless legs syndrome, SE = standard error, TG = triglyceride.

Table 4—Linear regression analysis of factors influencing VAS.

Variable	Coefficient (SE)	P
Female	-6.048 (10.524)	.038
Diabetic duration (years)	-0.624 (0.269)	.021
BMI (kg/m ²)	-0.558 (0.248)	.026
HbA1C (%)	-0.744 (0.925)	.422
FBS (mg/dL)	-0.02 (0.029)	.482
Smoker	-16.17 (5.442)	.003
Insulin use	-3.124 (3.170)	.326

Dependent variable is VAS and covariates are: sex, diabetic duration, BMI, HbA1C, FBS, smoker, and insulin use. BMI = body mass index, HbA1C = glycosylated hemoglobin, FBS = fasting blood sugar, SE = standard error, VAS = visual analog scale.

mobility problem and pain/discomfort aspects of the QoL are more affected by RLS. Adverse effect of RLS on QoL in patients with neuropathy was the same as those without neuropathy.

DISCUSSION

The prevalence of RLS in this cross-sectional study, carried out in a population of Iranian people with T2DM, was 19.5%,

of whom 51.2% also suffered from neuropathy. Patients with RLS were more likely to have poor quality of sleep (odds ratio 2.79; 95% confidence interval 1.30–5.99; $P = .008$); furthermore, they had a significantly lower QoL score compared to patients without RLS (0.83 versus 0.84, $P = .009$). However, there was no significant difference in QoL and sleep quality of the participants across the spectrum of RLS severity. Furthermore, RLS in the presence of neuropathy did not confer any additional burden on QoL and sleep quality compared to RLS without neuropathy.

The prevalence of RLS in our patients with diabetes (19.5%) is in line with the results of previous studies. Clinically significant RLS, although underdiagnosed,^{2,9} is common (2.7%) in the general population.² However, the prevalence of any form of RLS has been reported to range from 7% to 10%.^{2,25} Moreover, RLS is over four times more common in patients with diabetes than in the general population,⁸ with a prevalence of 10% to 42% in different populations with diabetes.^{26,27}

However, 51.2% of patients with RLS had neuropathy documented by nerve conduction studies. Peripheral neuropathy, one of the most common complications of diabetes, can mimic symptoms of RLS. Uncomfortable sensations of tingling, numbness, burning, and pain all are seen in both conditions, making it difficult to distinguish the two disorders.²⁸ However, some aspects of history and physical examination, as well as the nerve conduction test, can be used to differentiate neuropathy and RLS.²⁸ The fact that not all patients with diabetes and RLS suffered from neuropathy supports the results of previous studies in that neuropathy is not the only leading cause of RLS.²⁹

Poor sleep quality was seen in 38.1% of this population of patients with diabetes, and was associated with male sex, single status, high BMI, and presence of RLS. A large proportion of our patients with diabetes were found to have poor sleep quality, consistent with the previous studies in patients with diabetes.¹⁶ However, the relationship between diabetes and sleep disorders is a complex bidirectional relationship.³⁰ Marriage was a protective factor on quality of sleep among our studied population, similar to the results of another study that showed an elderly population who had ever married or lived with others had a better quality of sleep.³¹ However, in contrast to the results of previous studies,³² we could not find the protective effect of male sex on quality of sleep. This difference may be due to the difference in studied populations because the study of Denic-Roberts et al.³² was conducted among an adult population with long-standing type 1 diabetes in whom non-sex-specific prevalence of sleep disturbance did not differ from that of the general population. Like other studies, poor quality of sleep was also associated with high BMI.³³ Moreover, we found that patients with RLS were almost three times as likely as those without RLS to have poor quality of sleep. This finding strongly supports the results of previous studies regarding the role of RLS in sleep disturbance.¹⁷ Nevertheless, we found no association between some other variables, such as age, diabetic duration, smoking status, blood pressure, fasting blood sugar, HbA1C, total cholesterol, triglyceride, HDL, LDL, and poor quality of sleep. However, previous studies in this respect yielded conflicting results.^{34–36} These controversies may be due

to the difference in studied populations and applied methods. Moreover, there is a complex interrelationship between these demographic and clinical variables and sleep-related components that requires more comprehensive investigations for better understanding.

We also explored the QoL of our participants through EQ-5D-3L questionnaire. Advanced age, high BMI values, high HbA1C level, and being female were associated with lower QoL. Moreover, RLS lowers the score of QoL by 0.08. Considering the VAS part of the questionnaire, which indicates health status on the day of interview, we found lower scores for females, smokers, and patients with longer duration of diabetes and higher BMI. Furthermore, the mobility problem and pain/discomfort dimensions of the questionnaire were more affected by the presence of RLS. Patients with diabetes are known to have worse QoL than individuals without diabetes.³⁷ Our study supports the results of previous studies regarding the fact that being female,³⁸ advanced age,³⁹ higher BMI,³⁹ and poorer glycemic control⁴⁰ all are associated with lower QoL in patients with diabetes. In addition, we did not find any negative effect of duration of diabetes and insulin use on QoL, like some other studies.^{41,42} However, some controversies still exist about these findings.^{39,43,44} These controversies may be due to the influence of several factors such as the existence of other health problems, the presence of diabetes-related complications, living status (with family or alone), social relationship, and the level of education that obviously are not considered in all studies and may confound the results. Among the factors that affect QoL of patients with diabetes, RLS is more consistently associated with low QoL.^{2,12,45} It can adversely affect both physical and mental aspects of QoL.^{10,45} A study by Kushida et al. showed that RLS is associated with a unique burden on both mental and physical aspects of QoL in the general population, and this burden is even greater than that imposed by T2DM.¹⁰ Moreover, our study showed that RLS lowers QoL of the patients with diabetes, even more than obesity and high HbA1C level. Thus, physicians should pay as much attention on the evaluation and treatment of RLS as they do on the other predictors of poor QoL in patients with diabetes.

In addition, both RLS and neuropathy can interfere with sleep.²⁸ Furthermore, it is well established that RLS and neuropathy are independent predictors of poor QoL in patients with diabetes.^{45,46} Our study showed that although RLS impairs QoL of patients with diabetes, neuropathic RLS does not confer additive burden on QoL compared to RLS without neuropathy.

To our knowledge, this was the first study that addressed the prevalence and severity of RLS in Iranian people with T2DM and examined the role of RLS across the spectrum of its severity on both QoL and sleep quality of these patients. Another new aspect of our study is that we compared the effect of RLS with and without neuropathy on QoL and sleep quality of patients with diabetes. Furthermore, we excluded some other diseases such as CKD, OSA, and thyroid disorders that have the potential to affect the QoL of patients with diabetes.

However, the interpretation of the results has some limitations. First, because it is a cross-sectional study, determination of causality cannot be established. Second, evaluation of sleep was subjective and self-reported. Obviously objective

measures (eg, polysomnography) would offer more valid results. And finally, there were a few confounders that were not adjusted, such as diabetic-related complications other than CKD, some other comorbidities, socioeconomic factors, and education level that may have an important role in quality of sleep and QoL.

In conclusion, the prevalence of RLS in this population of Iranians with T2DM was 19.5%. A large portion of this population (51.2%) had a moderate form of RLS whereas a small number of them (4.9%) showed a very severe form of this disorder. Poor sleep quality was associated with being male, single status, high BMI, and the presence of RLS. Patients with RLS were almost three times as likely as those without RLS to have poor quality of sleep. In addition, poor QoL in this population of patients with diabetes was associated with being female, high level of HbA1C, high BMI, and presence of RLS. RLS lowers QoL score even more than HbA1C and BMI. Moreover, RLS affects the mobility problem and pain/discomfort aspects of QoL. Furthermore, RLS impairs the QoL and sleep quality of this population of patients with diabetes independently of the presence of neuropathy.

ABBREVIATIONS

BMI, body mass index
 CKD, chronic kidney disease
 EQ-5D-3L, EuroQol five-dimension questionnaire
 FBS, fasting blood sugar
 HbA1C, glycated hemoglobin
 HDL, high-density lipoprotein
 LDL, low-density lipoprotein
 PSQI, Pittsburgh Sleep Quality Index
 QoL, quality of life
 RLS, restless legs syndrome
 T2DM, type 2 diabetes mellitus
 TG, triglyceride
 VAS, visual analog scale

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DISCLOSURE STATEMENT

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