

## Risk Factor Analysis of Restless Legs Syndrome in Type 2 Diabetes Mellitus Patients

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### ABSTRACT

*Background: Diabetes is a global epidemic in India. The highest prevalence is estimated of 79.4 million by 2030. Diabetes Mellitus has been associated with secondary form of RLS. Aim: This study is to assess the possible risk factor for RLS development in Type 2 Diabetes Mellitus patients. Methods: This retrospective study focused on 120 Type 2 Diabetes Mellitus patients who were selected by using convenient sampling technique. The tool consisted of three parts: Part I was socio-demographic variables; Part II was clinical and Part III consisted of RLS rating scale. Result: The majority of the patients were with more than 10 years duration of Diabetes Mellitus, and 42.5% of the patients are obese. In relation to glycemic control, 67.5% of the patients were with HbA1c of more than 7. The majority of the patients (60.8%) were with raised fasting blood glucose and 74.2% of the patients with raised postprandial blood sugar level. There was significant association of severity of RLS with demographic variables like age, education, marital status, income, duration of diabetes, HbA1c, postprandial blood sugar, use of physical exercise, episode of hypoglycemia during last month and comorbidity at 0.05 levels. Conclusion: This study suggests that glycemic control has an association between RLS and type 2 diabetes mellitus subjects. Proper, early diagnosis and treatment of RLS may go a long way in reducing morbidity and probably mortality in diabetic patients.*

**Keywords:** global epidemic, risk factors, RLS, Type 2 diabetes mellitus

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### INTRODUCTION

Type 2 Diabetes Mellitus occurs when impaired insulin effectiveness (insulin resistance) is accompanied by the failure to produce sufficient cell insulin [1]. According to 2016 data of World Health Organization (WHO), globally, an estimated 422 million adults are with diabetes mellitus; of these, more than 90% are type 2 diabetics [2]. Diabetes mellitus is a major public health problem with serious complications. RLS has been significantly associated with diabetes, hypertension, obesity, and metabolic syndrome [3].

RLS (RLS) is a neurological disorder which causes unpleasant or painful sensations within the legs and a distressing, irresistible urge to move the legs [4]. It is also known as Willis-Ekbom Disease (WED) or Ekbom disease (EKD). The unpleasant feelings can happen on both sides of the body or on only one side, or they might start on one side and then move to the other. RLS symptoms range from mild to unbearable. They are generally worse in the evening and at night and may cause severe nightly sleep disruption. Symptoms almost go away in the early morning [5].

**The International RLS Study Group described the following symptoms of RLS (RLS)**

- Strange itching, tingling, or "crawling" sensations occurring deep within the legs; these sensations may also occur in the arms.
- A compelling urge to move the limbs to relieve these sensations.
- Restlessness: floor pacing, rubbing the legs, tossing and turning in bed.
- Symptoms may persist while lying down or sitting. Sometimes it may worsen while lying down or sitting and it improves with activity. In very severe cases, the symptoms may not improve with activity [6].

Diabetes Mellitus patients are more at risk of developing RLS than in the general population [7]. It is observed that majority of patients were developing complications which are non-compliance to treatment. Prevalence of RLS was 28.6% in diabetes patients. The aims of this study were to look for an association between RLS and type 2 diabetes and to identify the possible risk factors of RLS in diabetic patients.

**OBJECTIVE**

- To determine the risk factors of RLS among Type 2 Diabetes Mellitus patients.
- To associate the severity of the RLS with the demographic variables.

**METHODOLOGY**

This retrospective study focused on Type 2 Diabetes Mellitus patients who were present at the outpatients' endocrine department of selected hospitals in Coimbatore. A total of 120 samples were selected by using convenient sampling technique. The inclusion criteria for this study were: DM patients who were aged above 18 years and either sex; on outpatient department; able to speak and read Tamil and English and able to provide

informed consent to participate in the study. Patients were excluded if they had malignancies, tumors or multiple organ system failure, or any major surgical interventions in the previous 3 months.

**Data Collection**

The tool consisted of three parts:

- Part I was socio-demographic variables of study participants such as age, sex, marital status, religion, education, occupation, socioeconomic status, type of family, area of living, physical exercise, diet control, history of smoking, alcohol intake and coffee.
- Part II was clinical variables such as body mass index, HbA1c, duration of Diabetes Mellitus, mode of treatment, fasting blood sugar, postprandial blood sugar and comorbid illness.
- Part III consisted of RLS rating scale study group which contained 10 questionnaires and the score was given as follows: Very severe=31–40 points; Severe=21–30 points; Moderate=11–20 points; Mild=1–10 points; and None=0 points.

The ethical clearance was obtained to conduct this study. Informed consent was obtained before proceeding with the questionnaire. Researcher constructed tool was validated by experts and was pilot-tested on 10 patients at the outpatients department of the endocrinology and diabetology. Data was collected by interview technique with each study participant and some of the clinical data was obtained from the case sheets.

**Data Analysis**

Descriptive analysis for demographic variables and clinical variables was performed. Results were reported as numbers with percentages, mean and standard deviation for quantitative variables. Chi-square was computed to find the association between severity of RLS and socio-demographic and clinical variables.

**Table 1. Frequency and percentage distribution of socio-demographic variables (N=120).**

S. N.	Demographic Variables	Frequency (N=120)	Percentage (%)
1.	<b>Age (60.15±14.00)</b>		
	a) 18 to 34 years	12	10
	b) 35 to 50 years	21	17.5
	c) 51 to 65 years	41	34.2
	d) Above 66 years	46	38.3
2.	<b>Sex</b>		
	a) Male	73	60.8
	b) Female	47	39.2
3.	<b>Education</b>		
	a) Illiterate	25	20.8
	b) Primary School	32	26.7
	c) Higher Secondary	29	24.2
	d) Degree	34	28.3
4.	<b>Occupation</b>		
	a) Full time	53	44.2
	b) Retired	14	11.7
	c) Unemployed	33	27.5
	d) Others	20	16.8
5.	<b>Marital Status</b>		
	a) Married	82	68.3
	b) Unmarried	10	8.3
	c) Separated	12	10
	d) Widowed	16	13.4
6.	<b>Income</b>		
	a) <Rs. 5,000	20	16.7
	b) Rs. 5,001 to 15,000	47	39.2
	c) Rs. 15,001 to 5,000	29	24.1
	d) >Rs. 25,000	24	20
7.	<b>Smokes</b>		
	a) Smoker	56	46.7
	b) Ex-Smoker	14	11.7
	c) Non-Smoker	50	41.6
8.	<b>Drinking</b>		
	a) Alcoholic	60	50.00
	b) Ex-Alcoholic	20	16.7
	c) Non-Alcoholic	40	33.3
9.	<b>Takes Coffee</b>		
	a) Yes	73	60.8
	b) No	47	39.2
10.	<b>Use of Diet</b>		
	a) Yes	79	65.8
	b) No	41	34.2
11.	<b>Use of Physical Exercise</b>		
	a) Yes	55	45.8
	b) No	65	54.2

**RESULT**

Table 1 shows that 38.3% of patients were above 66 years of age, 60.8% of them were males 68.3% of patients were married, 46.7% of the patients had history of smoking, 50% of the patients had the history of taking alcohol and 60.8% of the patients took coffee.

**Table 2. Frequency and percentage distribution of clinical variables (N=120).**

S. N.	Demographic Variables	Frequency (N=120)	Percentage (%)
1.	<b>Duration of Diabetes Mellitus (14.65±8.24)</b>		
	a) <3 years	0	0
	b) 4 to 6 years	19	15.8
	c) 7 to 10 years	39	32.5
	d) >10 years	62	51.7
2.	<b>Mode of Treatment</b>		
	a) Oral hypoglycemic agents	79	65.8
	b) Insulin	15	12.5
	c) OHA and Insulin	26	21.7
	d) No Medication with Life Style	0	0
3.	<b>BMI (28.53±6.42)</b>		
	a) Underweight	14	11.6
	b) Optimal	20	16.7
	c) Overweight	35	29.2
	d) Obese	51	42.5
4.	<b>HbA1c (7.67±1.35)</b>		
	a) <7	39	32.5
	b) ≥7	81	67.5
5.	<b>Fasting Blood Sugar (148.92±36.56)</b>		
	a) Normal	47	39.2
	b) Raised	73	60.8
6.	<b>Postprandial Blood Sugar (191.87±37.72)</b>		
	a) Normal	31	25.8
	b) Raised	89	74.2
7.	<b>Experienced a Hypoglycemic Episode during the Last Month</b>		
	a) Yes	54	45
	b) No	66	55
8.	<b>Comorbidity</b>		
	a) <3	79	65.8
	b) ≥3	41	34.2

Table 2 shows that 51.7% of patients were with more than 10 years duration of Diabetes Mellitus, 65.8% of the patients were on oral hypoglycemic agents, 29.2 and 42.5% of the patients are overweight and obese respectively. In relation to glycemic control, 67.5% of the patients were with HbA1c of more than 7. The majority of the patients (60.8%) were with raised fasting blood glucose and 74.2% of the patients with raised postprandial blood sugar level. 55% of the patients had an experience of hypoglycemic episode during the last month. 65.8% of the patients were with less than three comorbidities.

The majority (32.5%) of the patients had very severe RLS and 29.2% of the patients

had severe RLS which is shown in Table 3.

Table 4 shows that there is significant association of severity of RLS with demographic variables like age, education, marital status, income, duration of diabetes, HbA1c, postprandial blood sugar, use of physical exercise, episode of hypoglycemia during last month and comorbidity at 0.05 level.

**Table 3.** Frequency and percentage of severity of RLS in patients (N=120).

S. N.	Severity	Frequency	Percentage
1.	Mild	13	10.8%
2.	Moderate	33	27.5%
3.	Severe	35	29.2%
4.	Very Severe	39	32.5%

**Table 4.** Chi-square association of severity of RLS with socio-demographic and clinical variables.

S. No.	Demographic Variables	Chi-Square	p-Value
1.	Age	20.89	0.01*
2.	Sex	5.99	0.1
3.	Education	40.40	0.00*
4.	Occupation	13.66	0.13
5.	Marital Status	29.85	0.00*
6.	Income	38.51	0.00*
7.	Smokes	6.61	0.35
8.	Alcohol	6.76	0.34
9.	Takes coffee	3.40	0.33
10.	Duration of Diabetes Mellitus	26.78	0.00*
11.	Mode of Treatment	7.20	0.30
12.	BMI	11.78	0.22
13.	HbA1c	9.02	0.02*
14.	Fasting Blood Sugar	6.85	0.07
15.	Postprandial Blood Sugar	12.52	0.00*
16.	Use of Diet	5.50	0.13
17.	Use of Physical Exercise	8.11	0.04*
18.	Experienced a hypoglycemic episode during the last month	10.86	0.01*
19.	Comorbidity	18.08	0.00*

\*Significant at 0.05 level.

## DISCUSSION

The present study aimed to find the risk factors of RLS in Type 2 Diabetes Mellitus patients. Mean age of patients suggests that RLS is most common in later life. Women were not significantly affected than men. Prevalence of RLS was witnessed with increases in age [8]. The same finding was noted in our study also.

Few studies' result showed that people who are obese, smoke or not physically active are prone for RLS [9, 10]. In our study, majority of the samples were with the history of smoking, alcoholic, takes coffee and with less physical exercise. Our study showed that majority of the patients was obese. A study demonstrated that a higher percentage of participants with BMI >27 kg/m<sup>2</sup> reported RLS symptoms compared to leaner individuals [11]. We found that physical activity has an effect on the risk of RLS on Type 2 Diabetes Mellitus patients. Increased lower extremity blood flow, release of endorphins, and increased release of dopamine brought on by exercise are among the possible mechanisms by which exercise could improve RLS symptoms [12].

The relationship between Cigarette smoking may trigger RLS. Our study shows that there is no association between smoking and RLS. The findings in a study suggest a statistically significant association between RLS and smoking at least one pack per day [13]. The current study suggested no significance with alcohol and these findings are in agreement with previous researches which have suggested an association between restless legs and alcohol abstinence [7].

Increased consumption of coffee or caffeinated beverages has been linked to RLS [14, 15]. The current study did not find a statistically significant association between coffee consumption and RLS risk. Our study suggests glycemic control is the main risk factor of RLS. The same finding was suggested by previous studies also.

## CONCLUSION

This study suggests that glycemic control has an association between RLS and type 2 diabetes mellitus subjects. Proper, early diagnosis and treatment of RLS may go a long way in reducing morbidity and probably mortality in diabetic patients.

## RECOMMENDATION

A similar study can be conducted with subject's family members. A similar study can be conducted with post-test to evaluate the regular practice of hand hygiene. There is a need for more research studies on nursing staff also.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interests regarding the publication of this paper.

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