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RESEARCH ARTICLE

The Prevalence and Risk Factors of Diabetic Peripheral Neuropathy and its Impact on Sleep Quality Among Adult Patients with Type 2 Diabetes Mellitus

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ABSTRACT

Objective: This study aims to evaluate the prevalence and risk factors of diabetic peripheral neuropathy (DPN) and its impact on sleep quality in adult patients with type 2 diabetes mellitus (T2DM) and to assess the relevance of other factors to sleep quality.

Materials and Methods: We recruited 549 patients with T2DM and conducted a self-administered questionnaire. We assessed sleep quality using the Pittsburgh Sleep Quality Index (PSQI) and the DPN using the Michigan Neuropathy Screening Instrument (MNSI). Additional information included descriptive data and metabolic profiles.

Results: The prevalence of DPN based on a history score of ≥ 7 was 31.7% and 33.7% based on physical examination based on a score of ≥ 2 using MNSI. Logistic regression analyses were conducted to identify risk factors independently related to DPN were smoking status, no diet regimen, no physical activity, no regular visit to treating physicians, cardiovascular disease, uncontrolled diabetes, diabetic retinopathy, lower HDL-cholesterol levels, duration of diabetes, and the type of medications (such as a statin, anti-hypertensive, and metformin). In addition, the results of the study revealed that the mean (±SD) PSQI score was 6.11(±7.01). The sleep disorder incidence rate was 32.8%. Cardiovascular disease, dyslipidemia, retinopathy, hypertension, and the type of medications (such as statin, and metformin) were the risk factors for poor sleep quality and glycemic control.

Conclusions and Recommendations: Peripheral Neuropathy and poor sleep quality are highly prevalent among Jordanian patients with T2DM. The results highlighted the need for intensive programs targeting early detection is needed to prevent late-onset DPN complications, even in asymptomatic patients. Moreover, the initial measures to prevent DPN and improve sleep quality include glycemic control and implementation with modification of lifestyle and behavioral changes such as appropriate diet, exercise, and regularly visiting treating physicians.

Keywords: Sleep Quality; Diabetic Peripheral Neuropathy; PSQI; MNSI; T2DM

Introduction

Diabetes becomes an epidemic disease in many economically increasing and newly industrialized countries, while people with diabetes are at increased risk of developing accelerated complications [1]. One of the most relevant complications is the development of diabetic peripheral neuropathy (DPN) [2]. About 60 to 70% of patients with diabetes have suffered from DPN. Several risk factors are with associated the development of DPN such as hypertension, obesity, and poor glycemic control were more likely to develop DPN [3-4]. On the other hand, people with DPN are associated with an impact on the quality of life [5-6]. Quality of sleep is an important constituent of quality of life. Poor sleep conjugates with depression, anxiety, impaired social functioning, chronic medical conditions, and mortality, which affects those patients [5-6]. The effect of DPN similarly affects the quality of sleep has been rarely investigated. The aims of this study were to the prevalence and risk factors of DPN and its impact on sleep quality in adult patients with type 2 diabetes mellitus (T2DM) and to assess the relevance of other factors to sleep quality. Results of the study may lead to an improvement in the services offered by healthcare professionals to the patients.

Materials and Methods

This study was cross-sectional in design conducted among adult patients (≥ 18 years) with T2DM who had regular follow-up visits at the Jordanian Ministry of Health (MoH) hospitals in Amman city, Jordan for at least six months. These hospitals provide services to the majority of patients with DM in all of Jordan, including those with or without health insurance. Children with Type 1 diabetes mellitus (T1DM) were excluded from the research because pediatric population beyond the goal of this research, adult diabetic persons who had an amputation surgery of the above-knee, whole foot, and below the knee amputations were excluded also from the research due to limited possibilities to examine them physically. The research was approved by the ethics committee at the MoH hospitals. Eligible patients gave written informed consent and the confidentiality of the statistics was assured. A total of 549 adult patients with T2DM were recruited from the general diabetes clinics attending the Jordanian Ministry of Health during the period from June 2018 to September 2018. An assessment instrument package was used in the current study. This package consisted of four parts including:

(1) Demographic data about participants (such as age, gender, education level, and smoking status) were achieved from the participants themselves. Clinical data were collected from the hospital records (such as height, weight, HbA1c, and therapy modalities). The consent form clearly detailed that information regarding clinical health indicators was to be extracted directly from each participant file.

(2) The prevalence and characteristics of DPN were estimated using the Michigan Neuropathy Screening Instrument (MNSI) was used to evaluate the presence of DPN [7]. MNSI is a well-known instrument used to assess DPN in patients with T2DM with a specificity of 95% and a sensitivity of 80%. The MNSI consists of a two-step program: I. History: neuropathic symptoms were assessed by a history questionnaire; consisting of 15 questions "Yes or No" on foot sensation including numbness, pain, and temperature sensitivity. The score ranges from 0 to 13 points and a score that is more than or equal to seven indicated the presence of neuropathic symptoms. II. Physical examination: was assessed by five variables (Appearance of feet, Identification of feet ulceration, Ankle reflex, Vibration sensation perception, Semmes Weinstein Monofilament (SWM) testing). On both feet and counted the total maximum of 10 points. If the patients score ≥ 2 points on a 10 points scale on the clinical section of MNSI then he was considered to have neuropathy.

(3) The quality of sleep was evaluated using Pittsburgh Sleep Quality Index (PSQI). The Arabic version of the PSQI is a 19-item self-administered questionnaire that evaluates sleep quality [8]. The 19 items comprise seven factors: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction. The score ranges from 0 to 21 points and a score that is more than or equal to eight indicated the sleep disorder of each patient.

Data were analyzed by using the Statistical Package for Social Sciences (SPSS, version 25). Data were described using mean values for continuous variables and proportions for categorical variables. The *t-test* was used to compare the means and *Chi-square* was used to test the independent distribution of categorical variables where appropriate. Binary logistic regression was used to identify independent predictors of DPN and sleep quality after adjusting all other potential confounders. A *p*-value less than 0.05 was considered statistically significant.

Results

Participants' characteristics

The study included a total of 549 T2DM patients aged between 31 and 88 years with a mean age of 58.56 years (*SD* = ±9.72). Their socio-demographic and clinical characteristics are shown in Table 1. More than half of the participants were females, 51% were unemployed and 62.1% were physically inactive. The mean BMI of study participants was 33 kg/m^2 (*SD* = ±6.17). The mean duration of diabetes was 7.74 years. More than half of the participants were females 51%. The majority of the study participants 84% had a family history of DM. 49% of the participants had uncontrolled HbA1c with a mean (±*SD*) of 8.72 (±3.21). Microvascular complications in the form of retinopathy and nephropathy were present in 23 and 18.9%, respectively. The majority of study subjects were having dyslipidemia and almost all patients with dyslipidemia were receiving statin therapy. Moreover, 31.3 and 75.2 % were having cardiovascular disease and hypertension, respectively (Table 1).

Prevalence of DPN

The prevalence of DPN among study participants was based on MNSI assessment, 31.7 and 33.7% of study participants had a score of ≥ 7 in the history questionnaire and a score of ≥ 2 in the physical examination section of the MNSI, respectively. The history questionnaire of the MNSI assessment showed that most of the participants had at least one symptom of the DPN. The most frequently reported symptoms in DPN patients were numbness and pain with walking which were present in 49.4 and 39% of study participants, respectively while, the least reported symptoms were a history of one or more toes amputations in legs/feet which was present in 8.2% of patients. Of those with DPN (174 patients), 34.6% of patients with DPN were males and 28.9% were females with a non-significant relationship between gender and DPN (p= 0.92). The prevalence of DPN for study participants using MNSI according to relevant socio-demographic, clinical, and laboratory characteristics is shown in Table 2.

Multivariate analysis of factors associated with DPN

Multiple logistic regression analysis showed that smoking status, not diet regimen, not physical activity, not regular visits to treating physicians, cardiovascular disease, uncontrolled diabetes, diabetic retinopathy, lower HDL-cholesterol levels, duration of diabetes, and the type of medications (such as a statin, anti-hypertensive, and metformin) were significantly associated with DPN. Smoker patients, who had not regular visits to treating physicians, physically inactive without a diet regimen were more likely to have DPN (Table 3). The likelihood of DPN was higher among patients with diabetic retinopathy and cardiovascular disease (*OR* = 3.197, *95% CI*: 10.605-5.635, $p < 0.001$, and *OR* = 2.376, *95% CI*: 5.774-20.057, $p < 0.001$), respectively. Subjects receiving anti-hypertensive and statin therapy were significantly associated with increased odds for DPN (*OR* = 1.736 and 3.539, respectively. Patients maintained on metformin therapy were less likely to have DPN (*OR* = - 4.549, $p = 0.001$) than those patients who aren't receiving metformin therapy. In addition, HDL-cholesterol levels ≥ 50 mg/dl subjects had significantly lower likelihood of having DPN than HDL-cholesterol levels < 50 mg/dl subjects with (*OR* =1.772, $p = 0.001$). Diabetes duration was the strongest predictor for DPN; compared to patients with T2DM for less than 5 years (*OR* = 0.266, $p = 0.001$).

The effect of DPN on patients' sleep quality

The results of the study revealed that the mean (±*SD*) PSQI score of the study patients was 6.11 (±7.01), with 32.8% who had a PSQI score ≥8, thus indicating poor sleepers. Bad sleeper rates are significantly higher in the DPN group compared with the patients without DPN ($p<0.05$) in Table 4. The relationship between DPN and PSQI components illustrates that subjective sleep quality, sleep duration, sleep disturbances, daytime dysfunction, and global PSQI correlated significantly with DPN ($p<0.05$).

Logistic regression analysis of risk factors associated with patients' sleep quality

The results showed a significant correlation between the duration of diabetes and patients' sleep quality with diabetes duration of more than five years were found more likely to have poor sleep than those who have diabetes for four years or less. As shown in Table 5, patients having cardiovascular disease, retinopathy, and hypertension disease were more likely to have poor sleep com-

pared to other groups, these values were considered to be significant (p<0.05). The results also revealed that subjects receiving statin therapy were more likely to have poor sleep compared to those subjects not receiving statin therapy with a statistically significant (p<0.05). The analysis shows that subjects who aren't receiving metformin therapy were more likely to have poor sleep compared to those subjects who are receiving metformin therapy, this value was statistically significant (p=0.005).

Variables	***N***	***%****	***Mean (±SD)***
Age group (year):			
< 50	89	16.2	
50- 69	368	67	58.56 (±9.72)
≥70	92	16.8	
Gender:			
Male	269	49	
Female	280	51	
Marital status:			
Single / Divorced and Widowed	60	10.9	
Married	489	89.1	
Working status:			
Unemployed	172	31.3	
Employed	155	28.2	
Retired	222	40.4	
Level of education:			
Illiterate	13	2.4	
Less than or equal to high school	235	42.8	
Diploma college	108	19.7	
Bachelor degree	163	29.7	
Master's or Doctorate degree	30	5.5	
Smoking status:			
Not smoker	267	48.6	
Ex-smoker	127	23.1	
Current smoker	155	28.2	
Diet regimen:			
Regular	271	49.4	
No diet regimen	278	50.6	
Physical activity:			
Regular	350	63.8	
No physical activity	199	36.2	
The family history of diabetes:			
Present	461	84	
Absent	88	16	
Regularly visit treating physician:			
Yes	380	69.2	
No	169	30.8	
HbA1C (%):			
Controlled < 7%	280	51	8.72 (±3.21)
Uncontrolled ≥ 7%	269	49	

Body mass index (BMI) (Kg/m²) **:			
Normal	38	6.9	
Overweight	151	27.5	33 (±6.17)
Obese	360	65.6	
Duration of diabetes (year):			
< 5	267	48.6	
5-11	156	28.4	
≥12	126	23	
Having hypertension:			
Yes	413	75.2	
No	136	24.8	
Having dyslipidemia:			
Yes	428	78	
No	121	22	
Having retinopathy:			
Yes	126	23	
No	423	77	
Having nephropathy:			
Yes	104	18.9	
No	445	81.1	
Having cardiovascular disease:			
Yes	172	31.3	
No	377	68.7	
Type of treatment:			
Insulin only	16	2.9	
Oral hypoglycemia agents only	340	61.9	
Oral hypoglycemia agents & Insulin	193	35.2	
Type of medication:			
On metformin			
Yes	408	74.3	
No	141	25.7	
On anti-hypertensive			
Yes	412	75	
No	137	25	
On statin			
Yes	419	76.1	
No	131	23.9	
HbA1C (%):			
Controlled < 7%	280	51	8.72 (3.21)
Uncontrolled ≥ 7%	269	49	

***Normal: 18.5–24.9, overweight: 25–29.9, and obese ≥ 30.*

** The sum of the percentage could be more than 100% due to rounding.*

Table 1: Socio-demographic, clinical, and laboratory data of the study participants

Variables	Neuropathy status				*P-value*
	With DPN *n= 174* (31.7%)		Without DPN *n= 375* (68.3%)		
	n	*%*	*n*	*%*	
Gender					
Male	93	34.6	176	65.4	0.92
Female	81	28.9	199	71.1	
Age group (year):					
< 50	3	3.4	86	86.6	
50 - 69	29	25	276	75	0.001**
≥70	90	97.8	2	2.2	
A family history of diabetes					
Present	149	32.3	312	67.7	0.277
Absent	25	28.4	63	71.6	
Duration of diabetes (year)					
< 5	0	0	267	100	
5-11	55	35.3	101	64.7	0.001**
≥12	119	94.4	7	5.6	
Having hypertension					
Yes	168	40.7	245	59.3	0.001**
No	6	4.4	130	95.6	
Having nephropathy					
Yes	103	99	1	0.1	0.001**
No	82	18.4	363	81.6	
Having cardiovascular disease					
Yes	131	76.2	41	23.8	0.001**
No	43	11.4	334	88.6	
Having dyslipidemia					
Yes	172	40.2	259	59.8	0.001**
No	2	1.7	119	98.3	
Having retinopathy					
Yes	115	91.3	11	8.7	0.001**
No	59	13.9	364	86.1	
Type of treatment					
Insulin only	15	93.8	1	6.2	
Oral hypoglycemia agents only	44	12.9	296	87.1	0.001**
Oral hypoglycemia agents & Insulin	115	59.6	78	40.4	

* = *Statistically significant, p05. 0<; ** = Statistically significant, p0.001 <.*

Table 2: Prevalence of DPN for patients with T2DM using MNSI according to relevant socio-demographic, clinical, and laboratory characteristics

Variables	*Odds Ratios (OR)*	*95% Confidence Interval Lower – Upper*	*P-value*
Marital status:			
Single/ Divorced and Widowed	1	0.900-12.584	0.071
Married	1.213		
Working status:			
Unemployed	1		
Employed	0.536	0.378-7.736	0.486
Retired	- 0.213	0.237-2.758	0.734
Smoking status:			
Not smoker	1		
Ex-smoker	2.368	2.265-50.308	0.003**
Current smoker	2.921	4.958-69.551	**0.001
Diet regimen:			
Regular	1	0.036-0.003	0.005**
No diet regimen	3.322		
Physical activity:			
Regular	1	0.004-0.103	0.001**
No physical activity	3.874		
Regularly visit treating physicians:			
Yes	1	0.057-0.076	0.012*
No	1.610		
Having cardiovascular disease:			
No	1	5.774-20.057	0.001**
Yes	2.376		
Having retinopathy:			
No	1	10.605-5.635	0.001**
Yes	3.197		
Having dyslipidemia:			
No	1	0.816-22.229	0.086
Yes	1.449		
Having hypertension:			
No	1	0.503-5.420	0.408
Yes	0.502		
HbA1C (%):			
Controlled < 7%	1	1.369-1.490	0.001**
Uncontrolled ≥ 7%	0.632		
Duration of diabetes (year):			
< 5	1	1.142-2.579	0.001**
≥ 5	0.266		
HDL-cholesterol levels:			
HDL < 50 mg/dl	1		0.001**
HDL ≥ 50 mg/dl	-104	0.852-0.953	
On metformin			
No	1	0.003-0.034	0.001**
Yes	-4.549		

On statin No Yes	 1 3.539	8.285-143.138	0.001**
On anti-hypertensive No Yes	 1 1.736	1.665-19.326	0.006**

(1) Reference group.

*** Statistically significant, p05. 0 <; ** = Statistically significant, p0.001 <.*

Table 3: Multivariate analysis of factors associated with DPN according to MNSI in patients with T2DM (*n = 174*)

Neuropathy status	Quality of sleep				*P-value*
	Good sleeper *n= 180*		Bad sleeper *n= 369*		
	n	*%*	*n*	*%*	
History of MNSI: Without DPN With DPN	 363 6	 86.8 3.4	 12 168	 3.2 96.6	 0.001**
Physical examination on MNSI: Without DPN With DPN	 362 7	 99.5 3.8	 2 178	 0.5 96.2	 0.001**

***Statistically significant, p < 0 .05; ** = Statistically significant, p < 0.001.*

Table 4: Association between sleep quality and DPN

Variables	*Odds Ratios (OR)*	*95% Confidence Interval Lower – Upper*	*P-value*
Type of treatment Insulin only Oral hypoglycemia agents only Oral hypoglycemia agents & Insulin	 1 - 0.679 1.004	 0.020 - 13.065 0.105 - 70.747	 0.682 0.546
On metformin No Yes	 1 - 5.403	 0.001 - 0.023	 0.005*
Having cardiovascular disease No Yes	 1 2.304	 5.423 - 18.505	 0.001**
Having dyslipidemia No Yes	 1 1.513	 0.888 - 23.227	 0.069
Having retinopathy No Yes	 1 3.233	 10.591- 60.655	 0.001**
Having hypertension No Yes	 1 2.108	 2.010 - 33.746	 0.003**
On statin No Yes	 1 4.374	 12.954 - 486.637	 0.001**

(1) Reference group.

*** Statistically significant, p < 0.05; ** = Statistically significant, p < 0.001.*

Table 5: Logistic regression analysis of risk factors with patients' sleep quality

Discussion

Diabetic patients with DPN may experience difficulty in managing their disease. Therefore, symptoms and signs of DPN are considered one of the most important factors when counseling diabetic patients. Literature across the world indicates that diabetes is associated with DPN [9-10]. Taking action to prevent further progression of the diabetes epidemic and its associated complications is the best solution. This study reported a high prevalence of DPN among patients with T2DM. The results are consentient with recent studies from the Middle East Region (MER) including Iran, Saudi Arabia, Korea, United Arab Emirates (UAE), and India [4, 10-12]. A study from southern Jordan by Elrefai et al (2009) was conducted to find out the prevalence of neuropathy among 229 patients with diabetic foot, which was found to be 89%. This prevalence was higher than our findings. This might be attributed to the differences in the sample selected which included complicated patients with a diabetic foot [13]. Al-Sarihin et al (2013) reported the prevalence of DPN at one hospital in Jordan to be 54.4% which was higher than the present study results, which can be explained with a different social demographics data sample [14]. The results found that most of the participants involved in our study had at least one symptom of the MNSI history questionnaire. Al-Sarihin et al (2013) showed that numbness was the most frequently reported symptom of DPN at 68.3% [14]. In Iran, tingling in the lower limb was the most frequently reported symptom of DPN [13]. Also, in the United Arab Emirates numbness, prickling feeling, burning pain, and pain with walking were the most prevalent symptoms of DPN [14]. Also, in Sri Lanka numbness of the feet was the most common symptom of DPN in cases of established DM, burning, prickling pain, or tenderness in newly diagnosed diabetic patients [15]. Since the quality of sleep is an important component of life quality, poor sleep may associate with depression, anxiety, impaired social functioning, chronic medical conditions, and mortality. Around 10% of people complain of one form of sleep disorder. This is particularly common in patients with DM [16]. We found that 32.8% of T2DM patients suffer from poor sleep quality. However, other studies which investigated this issue in diabetic patients reported different rates than ours. For example, Tsai et al. (2011) reported that 34.8% of Asian T2DM patients had poor sleep quality (global PSQI >8) [17]. A study done in the USA by Luyster et al. (2011) reported 55% of patients to be poor sleepers (PSQI score >5) [18]. The total PSQI mean score of our study was higher than in these studies and may be due to differences in sample size and cultural differences. Our study significantly correlated DPN with sleep quality. This suggests that signs and symptoms of the DPN improve when sleep quality becomes better. DPN has various symptoms such as spontaneously or trigger-induced chronic pain, burning, stabbing, sharp, cold pain, and neuropathic itch [19]. It was demonstrated that cases with DPN define pain-related interference in health-related quality of life (HRQoL) and experience several adverse consequences such as depression, fear, and sleep disturbances. This association might be explained by the fact that half of the diabetic patients with signs and symptoms of the DPN may suffer from painful diabetic neuropathy and osmotic diabetic symptoms, thus affecting their sleep quality by frequently visiting the bathroom during the night [20]. Glycemic control improves when sleep quality becomes well. This positive relationship was documented in several previous studies [17-18]. We showed patients having cardiovascular disease, retinopathy, and hypertension had a prediction for poor sleep quality. The data in the current study are consistent with several previous trials [21-22].

Conclusions and Recommendations

Peripheral Neuropathy and poor sleep quality are highly prevalent among Jordanian patients with T2DM. The results highlighted the need for intensive programs targeting early detection is needed to prevent and/or delay late-onset DPN complications, even in asymptomatic patients. The initial measures to prevent DPN and improves sleep quality include glycemic control and implementation with modification of lifestyle and behavioral changes such as appropriate diet, exercise, and regularly visiting treating physician. Moreover, as a positive association between The effect of DPN on patients' sleep quality in T2DM exists, it is recommended that all healthcare parties should be knowledgeable of the importance of the quality of sleep and DPN for those patients.

Declarations

Ethical approval and consent to participate

The study was conducted with the approval of the Jordanian Ministry of Health Ethical Board, Amman, Jordan, and the Near East University, Faculty of Nursing, Nicosia, Cyprus. All patients who volunteered to participate in the study gave written informed consent and the confidentiality of the information was assured. All procedures followed were in accordance with the ethical standards of the ISRCTN registry a primary clinical trial registry recognized by WHO and ICMJE.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Abu-Shennar JA, Alenezi I, Bayraktar N, Bebiş H, Şahin H, and Qassar QRS: Study conception and design, data collection, data analysis and interpretation, and preparation of the manuscript. Responsible and accountable for the accuracy or integrity of the work. Abu-Shennar JA, Alenezi I, Bayraktar N, Bebiş H, Şahin H, and Qassar QRS: Editing, drafting, and critical revision of the manuscript. All authors read and approved the final manuscript.

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