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Prevalence of Peripheral Neuropathy in Libyan Patients with Type 2 Diabetes Mellitus Using Semmes-Weinstein Monofilament Examination

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ABSTRACT

Diabetic peripheral neuropathy (DPN) is a common complication of diabetes mellitus (DM). However, there is very limited data available about the risk factors of DPN in the Libyan population.

Objective: To investigate the prevalence of DPN in Libyan patients with type 2 diabetes (T2D) and to find out its relation with patient demographics and associated risk factors including glycosylated hemoglobin (HbA1c), body mass index (BMI), duration of the disease, comorbidities, biochemical data, vitamin D, and vitamin B12 levels.

A cross-sectional study recruited 117 patients with type 2DM. Demographics (age, sex, and duration of DM), and BMI were all recorded. Laboratory results of fasting blood glucose (FBG), postprandial blood glucose (PPBG), Hemoglobin A1c, cholesterol, high-density lipoprotein cholesterol (HDL), low-density lipoprotein cholesterol (LDL-C), triglycerides, vitamin B12 and Vitamin D levels were all analyzed. DPN was assessed using the 10-g Semmes-Weinstein monofilament examination (SWME).

Among 117 type 2 diabetes patients, we found that 16/117 (13.68%) tested positive for the 10 g monofilament examination (DPN+ve). The mean age range was 57.53± 11.48 years, with a median diabetes duration of 10 years. BMI was 31.825.58± kg/m^2, and HbA1c was 8.55 ±1.99%. The study found that age, diabetes duration, FBG, and PPBG were the most significant risk factors for DPN. Binary logistic regression analysis revealed that only age, duration of diabetes, FBG, and PPBG were the only significant risk factors for DPN in our population and they predicted 73.8% of the model correctly.

Conclusion: The 10g monofilament test was effective in detecting early symptoms of DPN in 13.68% of patients with type 2 diabetes mellitus with older age, longer duration of diabetes, higher FBG and PPBG, and higher HbA1c as independent predictors of risk for DPN.

Keywords- Diabetic Peripheral Neuropathy; Type 2 Diabetes Mellitus; Prevalence.

INTRODUCTION

Diabetic peripheral neuropathy (DPN) is a common long-term microvascular diabetic complication. It is the most common form of neuropathies, and can lead to significant complications ranging from paresthesia to limb amputation.[1]

DPN has been defined as "the presence of symptoms and signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes" and may be present despite a lack of symptoms.[2]

One of the main risk factors for diabetic neuropathy is hyperglycemia, advanced age, hypertension, diabetes duration, dyslipidemia, smoking, and excessive alcohol consumption are all linked to more severe diabetic neuropathy symptoms.[3,4]

Early diagnosis of DPN allows for a better management and the prevention of foot ulcer formation.

The nerve conduction velocity (NCV) test is considered the gold standard for diagnosing neuropathy.[5] Furthermore, screening tools for the diagnosis of DPN were developed in the form of questionnaires including the Michigan Neuropathy Screening Instrument (MNSI), tuning fork testing, assessment of Achilles tendon reflexes, and tactile sensitivity with the 10-g monofilament.[6]

This study was aimed to investigate the prevalence and risk factors for DPN in Libyan patients with T2D.

MATERIALS AND METHODS

***Study population*:**

A cross-sectional observational study was conducted at the Almustaqpal Almosherq Centre, a private diabetes clinic in Tripoli, Libya, enrolling 117 diabetic patients from October to December 2022.

Inclusion criteria:

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Patients attending the clinic diagnosed with type 2 diabetes mellitus according to WHO 1999 criteria, aged ≥18 years. All participants provided informed consent after being informed about the study's objectives and benefits.

Exclusion criteria:

Patients with type 1 diabetes mellitus, those with lower limb amputation, individuals with psychiatric disorders that could affect study reliability, patients experiencing other forms of neuropathic pain (e.g., cancer-related or due to spinal cord injury), or those receiving medications potentially inducing neuropathy. Additionally, common diabetes-related neuropathies such as chronic inflammatory demyelinating polyneuropathy and uremic neuropathy were ruled out.

Data collection:

Data were collected using a structured data sheet during face-to-face interviews. The interviews recorded demographic information, diabetes history (duration, comorbidities, prescribed treatments for diabetes, neuropathic pain, and other conditions), as well as age, sex, and lifestyle characteristics (smoking status, dietary habits, and exercise).

Anthropometric measurements were obtained using a portable digital scale and stadiometer. Patients were instructed to stand erect for height measurement, and body mass index (BMI) was calculated.

Blood pressure was measured on the right arm using validated electronic sphygmomanometers after a 10-minute rest, with three readings averaged. Hypertension was defined as a mean systolic blood pressure ≥130 mm Hg, diastolic pressure ≥80 mm Hg, or the use of blood pressure–lowering medications. Cardiovascular disease was based on a self-reported history of coronary heart disease, heart attack, or stroke.

Nephropathy was determined by the presence of persistent albuminuria (30–299 or ≥300 mg/24 h urine collection), while diabetic retinopathy was diagnosed via dilated fundus examination by an ophthalmologist. Data on physical activity were collected using the short version of the International Physical Activity Questionnaire, which categorizes activity levels as low, moderate, or high (IPAQ, 2021).

Biochemical measurements:

Venous blood samples were used to assess fasting serum lipids, glycosylated hemoglobin (HbA1c), fasting and postprandial blood glucose (FBG and PPBG), and serum creatinine. Urine protein was categorized as negative (<15 mg/dL), trace (15–30 mg/dL), + (30 mg/dL), ++ (100 mg/dL), +++ (300 mg/dL), or ++++ (>1000 mg/dL). Uncontrolled diabetes is defined as having an HbA1c level of 7% or higher.

Hypercholesterolemia was defined as total cholesterol ≥ 240 mg/dL. Dyslipidemia was defined as triglycerides >150 mg/dl (1.7 mmol/l), low-density lipoprotein -cholesterol (LDL-c) >100 mg/dl (2.6 mmol/L), or HDL cholesterol <40mg/dl (1.0 mmol/l) in men and <50 mg/dl (1.3 mmol/l) in women based on American Diabetes Association (ADA) criteria.

***Screening of DPN*:**

Patients removed their shoes and socks. A trained technician then applied a light 10g Semmes-Weinstein monofilament (Baseline, Fabrication Enterprises, USA) sequentially at four sites on each foot specifically, on the plantar and dorsal aspects of the first and fifth metatarsal heads. With their eyes closed, participants identified the location where they felt the pressure. Areas with calluses were avoided. If a patient failed to correctly detect the pressure stimulus, the test was repeated (up to three times) at that particular site. Loss of protective sensation in any of these sites was taken as evidence of diabetic peripheral neuropathy.[7]

***Statistical Analysis*:**

Data were analyzed using SPSS 22.0 for windows (IBM Corp., Armonk, NY, USA). Normally distributed variables are reported as means ± SD, and skewed variables as medians (interquartile range). Group comparisons utilized Student's t-test or Mann-Whitney U-test for continuous data and the χ^2 test for categorical variables. The relationship between neuropathy outcomes and diabetic retinopathy was assessed via Spearman's correlation, while multivariate logistic regression identified independent predictors of peripheral neuropathy. A P-value <0.05 was considered statistically significant, and tables and graphs were produced using Microsoft Excel.

RESULTS

Participants' characteristics

A total of 117 patients with type 2 diabetes were enrolled, including 84 females (71.79%) and 33 males (28.21%), aged between 25 and 83 years. The overall mean age was 57.53 ± 11.48 years, with no statistically significant difference between males and females (55.60 ± 12.58 vs. 57.12 ± 11.14 years, respectively; P= 0.414). The highest prevalence of diabetes was observed among participants aged 41–60 years (52.4%).

The median duration of diabetes among all participants was 10 years [IQR: 4–12], with no significant gender difference (10.0 years [IQR: 9.0–11.0] in males vs. 9.0 years [IQR: 4.0–12.0] in females; P = 0.173). Approximately half of the patients (51.3%) had been living with diabetes for more than 10 years.

The mean HbA1c was 8.55 ± 1.99%, with 77.8% of patients having poor glycemic control. Males had significantly higher HbA1c levels than females (P = 0.022).

Comorbidities were present in 56.4% of patients, mainly dyslipidemia (63.3%) and cardiovascular disease (49.6%). Diabetic retinopathy and nephropathy were found in 16.2% and 1.7% of patients, respectively.

Only 28.2% had good glycemic control (HbA1c ≤7%), while 71.8% were poorly controlled (HbA1c >7%).

The study cohort was predominantly managed with oral hypoglycemic agents alone (64.1%), with insulin monotherapy used in (11.97%) of patients and a combination of oral agents with insulin in (23.93%). The majority of participants were non-smokers (88.89%), though only (28.21%) reported being physically active.

Participants had a mean BMI of (31.82 ± 5.58 kg/m²). Although female patients exhibited a slightly higher BMI (32.42 ± 5.15 kg/m²) than males (30.42 ± 6.41 kg/m²), the difference was not statistically significant ($P = 0.086$). Among the 117 patients, (63.25%) were obese with females comprising (78.38%) of the obese subgroup (23.93%) were overweight, and (12.82%) had normal body weight.

Prevalence of peripheral neuropathy

Sixteen out of 117 patients (13.68%) tested positive in the 10 g monofilament test (DPN +ve), while 101 (86.32%) tested negative (DPN –ve) (Figure 1). The mean age of (DPN +ve) patients was significantly higher (68.13 ± 11.27 years) than that of DPN –ve patients (55.85 ± 10.36 years, $P < 0.001$).

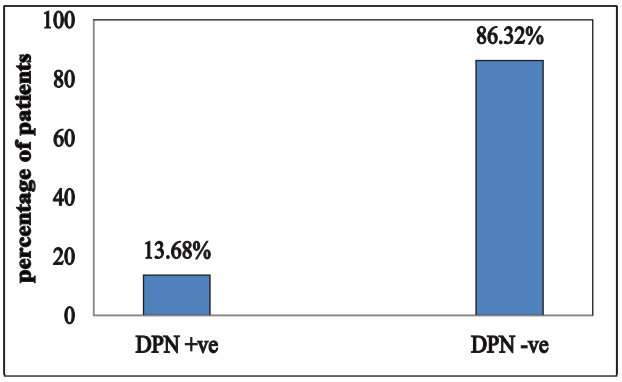

Figure 1: Response to Semmes-Weinstein Monofilament Test.

Furthermore, Patients with (DPN +ve) also demonstrated longer duration of diabetes (15.50 years [IQR: [13.0-20.75]) years vs. 9.0 years [IQR: 5-11]) years, p<0.001), higher HbA1c (9.74 ± 2.46 vs. 8.36 ± 1.85, P =0.009, and higher FBG and PPBG (197.5 mg/dl [IQR: 169.50-293.0] vs. 149 mg/dl [IQR: 125.50-183]), $P = 0.001$ and (200 mg/dl [IQR: 180-253.75] vs. 169 mg/dl [IQR:147-199.5]), P =<0.001 respectively, in comparison to (DPN-ve) patients. There was no gender-based difference in the prevalence of DPN ($P = 0.759$) (Table 1).

Additionally, within the DPN +ve group, the SWMT test was positive in 13.33% of patients with a diabetes duration ≤10 years and in 86.67% of those with a duration >10 years, demonstrating a significant association ($P = 0.001$).

Table 1: Demographic characteristics, clinical and laboratory data of (DPN +ve) and (DPN -ve) patients

Clinical characteristics	(DPN +ve) (n=16)	(DPN -ve) (n=101)	P-value
Gender, n			
Male	4	29	0.759
Female	12	721	
Treatment type, n			
Insulin	3 (18.75%)	11 (10.89%)	0.629
Oral hypoglycemic	10 (62.50%)	65 (64.36%)	
Combination	3 (18.75%)	25 (24.75%)	
Mean ± SD			
Age, years	68.13±11.27	55.85±10.36	<0.001
Weight, kg	83.9±12.50	82.4±17.31	0.730
Height, m	1.6±0.10	1.6±0.11	0.971
BMI, kg/m2	32.7±5.92	31.7±5.54	0.467
HbA1C, (%)	9.74± 2.46	8.36 ± 1.85	0.009
LDL, mg/dl	84.6±35.05	95.8±37.20	0.260
Cholesterol (TC), mg/dl	142.3±45.24	154.1±44.13	0.322
Systolic BP, (mmHg)	138.8±22.17	136.2±16.58	0.591
Median [Interquartile Range]			
Duration of DM, years	15.50 (13-20.75)	9.0 (5-11)	<0.001
VitaminB12, ng/ml	436 (269.25-500)	378 (300-500)	0.769
FBG, mg/dl	179.5 (169.50-293.0)	149 (125.50-183)	0.001
PPBG, mg/dl	200 (180-253.75)	169 (147-199.5)	<0.001
HDL, mg/dl	45 (43-53.50)	45 (36.50-55.0)	0.821
Triglycerides, mg/dl	104.0 (86.72-167.28)	142.6 (142.0-175.14)	0.062
Diastolic BP, (mmHg)	80 (80-80)	80 (80-90)	0.583
Vitamin D, ng/ml	21.5 (15.75-33.75)	21.0 (14.38-30)	0.816

The mean values for total cholesterol (TC), high-density lipoproteins (HDL), low-density lipoproteins (LDL), triglycerides, Systolic and diastolic blood pressure, vitamin D, and B12 levels were not significantly different in the two groups.

There was a statistically significant association between DPN and diabetic retinopathy ($P = 0.023$), while

nephropathy was not a significant predictor of DPN in patients with DM (P =0.079).

Physical activity was statistically insignificant in (DPN +ve) patients as compared to the (DPN -ve) group (P = 0.952). The majority of (DPN +ve) patients were treated with oral hypoglycemic drugs (62.50%). However, the type of drug therapy was statistically insignificant in (DPN +ve) patients as compared to the (DPN -ve) group (P =0.629).

The variables that were found significant in the univariate analysis (age, duration of diabetes, HbA1c, FBG, and PPBG) were entered as independent variables in the logistic regression model. The results of the logistic regression analyses showed that data have been only partly confirmed, with the age of the participants (OR= 1.160, 95% CI: 1.027-1.309, P = 0.016), fasting blood glucose (OR=1.020, 95% CI: 1.006-1.034, P = 0.004), and postprandial blood glucose (OR=1.033, 95% CI: 1.010-1.057, P = 0.005), duration of diabetes (OR=1.428, 95% CI: 1.116-1.827, P =0.005) were significant risk factors for diabetic peripheral neuropathy in our population (Table 2). R2= 0.738 (Nagelkerke R2), indicating that logistic regression analysis predicted 73.8% of the model correctly.

Table 2: Binary Logistic Regression Analysis of DPN-Related Risk Factors

Variables	B	.Sig	(Exp(B	(C.I.for EXP(B 95%	
			Lower	Upper	
Age	0.148	016.	1.160	1.027	1.309
FBG	0.020	004.	1.020	1.006	1.034
PPBG	0.033	005.	1.033	1.010	1.057
HbA1C	0.356	819.	1.045	0.716	1.527
Duration	0.356	005.	1.428	1.116	1.827
Constant	-26.265	000.	0.000		

DISCUSSION

The study aimed to find the prevalence of DPN in patients with T2D using the SWME 10 gm monofilament testing, and to examine the links between its occurrence and the various risk factors. Understanding these factors is crucial for developing effective strategies for early detection and management of DPN.

The 10 gm SWME is a non-invasive, inexpensive, easy and accurate hand held calibrated nylon thread, which buckles when a force of 10 gm has been exerted on it, and delivers a standard, reproducible indication of the patient's ability to sense a point of pressure.[8,9]

One typical consequence in people with diabetes mellitus is diabetic peripheral neuropathy. According to Boulton (2014)[10], 50% of diabetics will get a foot ulcer at some point in their lives, while Vinik (2003)[11] reports that DPN is a factor in 50-75% of nontraumatic amputations. DPN can have depressing side effects, such as neuropathic foot pain and diminished feeling, which can lower quality of life and lead to anxiety, insomnia, and depression.[12]

Approximately 6 to 51% of all diabetes individuals have DPN. Following 13-14 years of disease progression, the prevalence of DPN in individuals with type 1 diabetes rises to 29-36%.[2,13] In individuals with type 2 diabetes, this prevalence is slightly higher and is estimated at 42-45% in young individuals with the disease.[14]

Numerous studies have shown that advanced age, long-term diabetes, poor glycemic control, obesity, hypertension, dyslipidemia, and cigarette smoking are the most prevalent risk factors for DPN.[15-17] The majority of these risk factors are modifiable with early evaluation and appropriate action.

Furthermore, the financial strain of treating DPN and its after effects places on national health authorities across the globe. Because there is typically no systematic early screening, DPN is frequently detected at a late, pre-ulcerative stage. It becomes imperative to screen DM patients for DPN at the earliest stage to minimize the deleterious consequences of its severe complications. Diabetic foot ulcer risk is successfully predicted by screening for outpatient and community settings. However, it is unlikely that developing nations have access to contemporary equipment for the treatment of DPN patients.[18]

In our study, the majority of participants were women (71.79%). This gender difference is consistent with previous case-control and cross-sectional studies,[19,20] this may be related to gender-based healthcare-seeking behaviors as women tend to seek primary care services more than men.[21] No sex-specific differences were observed in the mean age of participants, this result is in agreement with previously published studies.[22,23]

In our study, a Semmes Weinstein examination has shown a prevalence of DPN of 13.68%. The presence of DPN was associated with older age, longer duration of diabetes, higher HbA1c, high FBG, and PPBG.

The uncertainty and diversity in estimating the prevalence of DPN in different countries are to a large extent due to the diversity in the diagnostic criteria and sampling methods.[24] In addition, the prevalence of DPN varies widely and is heavily dependent on the type of diabetes, different demography of the study population, and definitions of DPN, including the degree of control of the hyperglycemia.[25]

In our study, the univariate analysis showed that patients aged more than 60 years, those with a longer duration of diabetes, those with uncontrolled glycemic status, and the presence of retinopathy were more susceptible to developing DPN.

We found no significant gender-based difference in the prevalence of DPN (P = 0.759). This result was reported by Bansal *et al*. (2014)[22], as well by Aleidan *et al*. (2020)[26], though other published studies had reported that the male gender is a significant risk factor.[27,28] On the contrary, others have reported that women were more likely affected by DPN than men (29.49% vs. 23.37%) irrespective of their age groups.[19]

The current investigation demonstrated a strong association between the duration of T2DM and the occurrence of DPN (OR = 1.428, 95% CI: 1.116-1.827, P = 0.005). This strong positive correlation was demonstrated in previous studies.[29-31] The results of this study have revealed that age (OR 1.160, 95% CI: 1.027-1.309, P = 0.016) was significantly associated with DPN. Other studies have confirmed the association of age as a risk factor for DPN among patients with T2DM.[32,33] The molecular basis of aging and aging-related changes is still not fully understood. It is generally accepted that aging is driven by a time-accompanied accumulation of molecular and cellular damage.[26]

The microvascular complications in DPN are usually related to the duration of illness where diabetic nephropathy took a longer time to develop,[22,23,34] other studies reported that retinopathy can be detected in nearly every patient after a diabetes duration of 20 years,[35] suggesting that early screening is important to prevent and delay the occurrence of microvascular complications.

In agreement with other reports, our data revealed that the occurrence of DPN was significantly highly correlated (P =00003) with diabetic retinopathy in Libyan patients.[36] Patients with T2DM could develop chronic kidney disease in the form of diabetic nephropathy which is often associated with DPN.[37] However, this association was lacking in our study (P =0.079). Although the prevalence of microvascular diabetic complications is related to the degree of glycemic control, a treatment goal for HbA1c (<7%) was set by the ADA to prevent developing these complications.[38]

Previous studies suggested that smoking was the most common risk factor for the development of vascular complications including DPN in T2DM.[39,40] In this study, the effect of smoking was not statistically significant, this could be attributed to the fact that all female patients, though they constitute 71.79% of the participants were non-smokers.

We found no significant association between the modality of antihyperglycemic medication and DPN (P =0.629) with the majority of participants in both groups using oral hypoglycemic drugs. Khawaja *et al*.[41] have concluded that the antihyperglycemic treatment could play a role in attenuating the development and progression of diabetic neuropathy.[42] Oral hypoglycemic agents (OHA) provided protection against DPN as opposed to insulin therapy (OR 0.639, 95% CI:0.44-0.29, P = 0.016).[41]

Metformin, an oral hypoglycemic medication, inhibits oxidative stress associated with primary neuron death, which results in anti-inflammatory and direct nerve protecting actions.[43,44] Additionally, Kostav *et al*. found that among newly diagnosed diabetics in Germany and the UK, insulin use was one of the highest risk factors for DPN.[45]

Our data highlighted the need to emphasize the necessity of an intensified, proactive screening targeting T2DM patients with high risk for developing DPN and prompt implementation of health education in patients with older age, uncontrolled glycemic status, retinopathy, and patients with long-standing diabetes.

There are certain limitations on the current study as well. First, a modest sample size was examined initially. Second, the result was lacking the comparison with definitive diagnostic techniques, such as measuring nerve conduction velocity (NCV) and using the Michigan Neuropathy Screening Instrument (MNSI) to confirm neuropathy. Third, we did not assess the role of hypothyroidism, folic acid deficiency, or genetics in DPN other than diabetes. Furthermore, there is a glaring disparity in the proportion of male and female patients, making it difficult to do a thorough direct comparison of how gender functions as a risk factor in DPN. Lastly, because this study is cross-sectional, it is unable to assess the long-term impacts of risk variables on the development of DPN. However, with the establishment of a register, we possibly could implement those longitudinal measures in future studies.

CONCLUSION

Diabetic peripheral neuropathy is a common complication among type 2 diabetic patients. The prevalence of DPN in this study was 13.68%. Age, diabetes duration, FBG, and PPBG were the associated risk factors. Since DPN poses a formidable threat to patients with diabetes, early and comprehensive neurological screening is recommended in patients with associated risk factors.

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