Original Article

Prevalence of painful diabetic peripheral neuropathy and its impact on quality of life among diabetic patients in Western region, Saudi Arabia

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Abstract

Background: Diabetic neuropathy is the most common long-term complications of diabetes, frequently presenting as painful diabetic peripheral neuropathy (PDPN), which can significantly impair patients' quality of life (QOL). This study set to estimate the prevalence of PNPD and health-related quality of life (HRQoL) in the setting of primary health care in Saudi Arabia. **Methods:** This study was conducted in primary health-care centers affiliated with the National Guard Health Affairs in Western Saudi Arabia. Arabic version of the Douleur Neuropathique 4 questionnaire was administered on diabetic patients to screen for neuropathic pain and short-form 12 questionnaire to assess HRQoL. **Results:** The study screened (n = 349) Type 2 diabetic patients. The prevalence of PDPN was 33.2%. PDRN was more likely to affect females (adjusted odds ratio ["AOR"] =1.96, P = 0.024), and those living with diabetes for over 15 years (AOR = 2.26, P = 0.039), and those on insulin treatment (AOR: 2.33, P = 0.010) alone or in combination (AOR = 1.78, P = 0.034). Both physical and mental components (MCs) of QOL scores were significantly higher in diabetic patients without PDPN compared to those with it; 49.57 ± 9.31 versus 40.77 ± 8.14 for physical component QOL and 51.72 ± 9.36 versus 44.35 ± 8.12 for MC QOL, P < 0.001. **Discussion and Conclusion:** Painful peripheral neuropathy is relatively common among type 2 diabetic patients in Western Saudi Arabia and impacts both physical and MCs of the QOL of affected patients.

Keywords: Diabetic, health-related quality of life, painful diabetic neuropathy, Saudi Arabia, Western region

Introduction

Diabetes mellitus (DM) constitutes a growing global problem. It is a chronic disease with huge personal sufferings and negative financial implications. DM affects 425 million people worldwide, over 8% of all adults of 20–79 years age. This very proportion is expected to rise to 10% and nearly 629 million of people will have DM by 2045.[1]

The current Saudi Arabian DM prevalence is 18.5%,[2] substantially surpassing the global (8.8%) and the regional (10.7%) figures.

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Hence, Saudi Arabia is among the countries with the highest magnitude of the disease.[3]

Diabetic neuropathy is the most common long-term complications of DM, and it is the leading initiating factor for foot ulceration, Charcot neuroarthropathy, and lower extremity amputation.[4] One of the common types of diabetic neuropathy is painful diabetic peripheral neuropathy (PDPN), described as a superficial burning pain associated with other sensory symptoms that affect the lower extremities.[5-7] PDPN is extremely common in Saudi Arabia and is estimated to affect 65.3% of diabetic patients.[8] PDPN significantly alters the patients' quality of life (QOL).[9-12] Notably, QOL is defined by the World Health Organization as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns."[13] The prevalence of PDPN among Saudi patients in the primary care setting was estimated in a recent investigation at 35%,[14] although their use Michigan Neuropathy Screening Instrument, instead of the more accurate Douleur Neuropathique 4 (DN4) tool, remains questionable as it may have underestimated prevalence measures.[15] The regional estimated for PDPN varied considerably according to setting, population, country, and tool used. They ranged between 13.7% in Iran,[16] 32.2% in Kuwait,[17] 23% in Turkey,[18] and 53.7% among Egyptian, Lebanese and Jordanian patients,[19] and 42.2% in Libya.[20] Similar picture in terms of PDNP point prevalence emerged among international surveys. Proportion of DM patients who developed PDPN was 44.5% in Nigeria[21] and 30.6% in Taiwan[22] for instance. Studies across the world established an inverse association between PDNP and health-related quality of life (HRQoL). Substantial reduction in HRQoL, both physical and mental components (MCs), was noted in the samples of DM patients from Spain,[23] France,[24] and Belgium.[9]

No published data, to the best of our knowledge, are available on PDPN prevalence, or impact on QOL, among diabetic patients who live in the Western Region, Kingdom of Saudi Arabia (KSA). This study aimed to estimate the prevalence of PDPN, its impact on patients' QOL and to determine its predictors.

Methodology

This was a descriptive, cross-sectional investigation conducted between May and December 2019 on diabetic patients selected from diabetic patients Type 2 who attended the local primary health-care centers affiliated with the National Guard Health Affairs in Western Saudi Arabia (namely, King Khalid Residential City Clinic [Taif Housing] in Taif city, Sharia center in Makkah city, Specialized polyclinic, Al-Iskan center and Bahra center in Jeddah city). The study was approved at King Abdul-Aziz Medical City, Ministry of National Guard-Health Affairs Jeddah.

Patients were included if they were over 25 and under 65 and had confirmed the diagnosis of Type 2 DM. They were excluded if they had comorbid neurological disorders, malignancy, history of nerve root compression, other pain conditions unrelated to diabetic peripheral neuropathy, or alcoholism.

Based on 65.3% PDPN prevalence,[8] and 80% power, 5% significance, a sample size of (n = 348) was required for the study.

We adopted the random cluster sampling technique. Patients were sampled randomly and equally (n = 87) from each of the four centers.

The data were collected by using an interview-administered questionnaire consisting of 3 parts. The first part constituted the personal demographic and clinical data about diabetes. The second part includes the Arabic version of the DN4 questionnaire which is valid and reliable screening tool for neuropathic pain whose Cronbach's value was 0.67. DN4 includes 10 items; 7 items are based on an interview with the patient that related to pain quality (i.e., sensory and pain descriptors) and 3 items based on the clinical examination. A score of 4 was found to be the best cutoff for the diagnosis of neuropathic pain.[25] The third part includes the application of Arabic HRQoL short-form (SF12) questionnaire, whose Cronbach's was 0.84 considered very good reliability level.[26] It has two components: physical component (PC) and a MC. The scoring system used for scoring of the SF12 questionnaire was based on work by Ware *et al.*[27]

With the consent of target institutions and treating physicians, all patients fitting the inclusion criteria were recruited while waiting for their turn in the clinics waiting areas on random days after making sure the diabetes clinics were available. Questionnaires were filled out through a face-to-face interview for each patient. Interviews took an average of 10–15 min to be completed. Interviews were conducted on different days of the week and at varying times to ensure a representative cross-sectional sample of patients. The nurses in charge at the clinics introduced the study to all eligible patients present in the waiting areas before visiting the physicians during the follow-up visits. Some of trained medical interns were involved to help in data collection. They underwent comprehensive training in questionnaire administration and interviewing techniques. In addition, weekly meetings of the research team were held to ensure the inter-rater reliability and the standardization of data collection protocol. Each participant was interviewed only once.

Health-care providers responsible for the treatment of interviewed patients were not present during the interviews. The participants were assured that any information they reveal will remain confidential and will be strictly used for research purposes only. Patients were not paid to take part in the study and were informed that they are free to decline answering any questions they will not be comfortable with. Signed consent forms were obtained from all participating patients. Research data, both soft and hard copies, were maintained in a secure location and/or unit within NGHA premises and were only accessible by the Research Team.

The data were checked for completeness, and responses were coded and entered into the Statistical Package for the Social Sciences (SPSS) software version 25 for Windows. Then results were tabulated, graphically and statistically analyzed. Categorical variables were described in the form of frequency and percentage, whereas continuous variables were summarized by mean and standard deviation. Comparisons between the variables were made by using the Chi-squared test (bivariate analysis). Multivariate logistic regression model was utilized to evaluate the impact of covariates on PDPN. $P = 0.05$ was used to determine the statistical significance.

The study was granted ethical approval on April 23, 2019, by Biomedical Ethics Section of King Abdullah International Medical Research Centre's International Review Board Office, affiliated to the Health Affairs Department of the Ministry of National Guard; Memo Ref No. IRBC/0560/19.

Results

A total of $n = 349$ patients with DM participated in this investigation. Over 43.9% of them exceeded 55 years in age. Females were 56.4% and 46.2% were illiterates, whereas 7.8% were university or above graduated [Table 1]. Of all participants, 54.1% were obese and 35.2% were overweight, as illustrated in Figure 1.

The duration of diabetes ranged between 5 and 10 years among 30.6% of the patients, while it exceeded 15 years in 27.5% of them. Glycated hemoglobin, unfortunately, exceeded 7% among most of the participants (72.8%). More than half of the patients (56.3%) were treated by oral hypoglycemic drugs only, whereas 9.8% were treated by insulin only and 32.2% were treated by a combination of both Table 2 summarizes the diabetes-related characteristics of the participants.

Participants' responses to the DN4 questionnaire are on display in Table 3. Burning sensation was reported by 43% of DM patients and numbness in the same area of pain by 46.4%. Physical examination revealed hypoesthesia to touch in the same pain location in 12.9% of patients. The pain was accentuated by brushing in 4.6% of cases. The prevalence of PDPN in our DM sample was 33.2%, as shown in Figure 2.

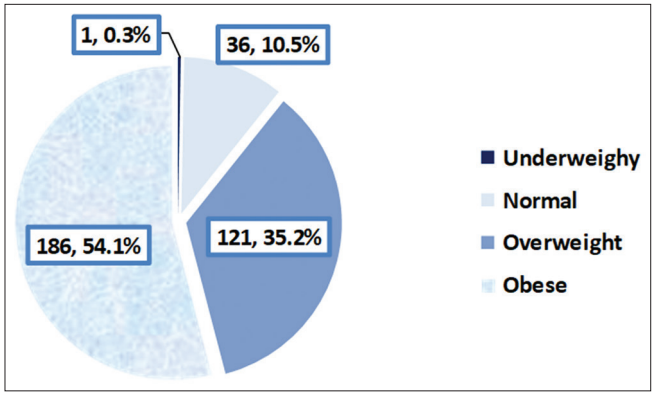

Figure 1: Body mass index of the participants

Women were more likely to have PDPN compared to men (40.6% vs. 23.7%, $P = 0.001$). Illiterate patients had the highest rate of PDPN (41.6%), whereas those with intermediate school education had the lowest rate (19%), $P = 0.007$. Concerning body mass index (BMI), normal participants had the highest

Table 1: Demographic characteristics of the patients

	n (%)
Age (years)	
25-35	5 (1.4)
36-45	42 (12.0)
46-55	114 (32.7)
>55	188 (43.9)
Gender	
Male	152 (43.6)
Female	197 (56.4)
Educational level (*n*=348)	
Illiterate	161 (46.2)
Elementary school	72 (20.7)
Intermediate school	42 (12.1)
High school	46 (13.2)
University/above	27 (7.8)

Table 2: Diabetes-related characteristics of the participants

	n (%)
Duration of diabetes (years)	
<5	91 (26.1)
5-10	107 (30.6)
11-15	55 (15.8)
>15	96 (27.5)
Glycated hemoglobin (%) (*n*=342)	
<7	93 (27.2)
7-8	96 (28.1)
8.1-9.5	77 (22.5)
>9.5	76 (22.2)
Medication for diabetes (*n*=348)	
None	6 (1.7)
Oral hypoglycemic	196 (56.3)
Insulin	34 (9.8)
Oral hypoglycemic and insulin	112 (32.2)

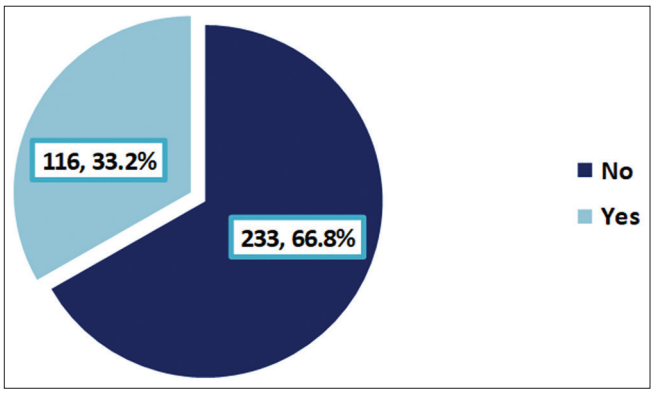

Figure 2: Prevalence of painful diabetic peripheral neuropathy among Type 2 diabetic patients

Table 3: Response of the participants to the Douleur Neuropathique 4 questionnaire

	Yes, *n* (%)	No, *n* (%)
Does the pain have one or more of the following characteristics?		
Burning	150 (43.0)	199 (57.0)
Painful cold	94 (26.9)	255 (73.1)
Electric shocks	79 (22.6)	270 (77.4)
Is the pain associated with one or more of the following symptoms in the same area?		
Tingling	124 (35.5)	225 (64.5)
Pins and needles	111 (31.8)	238 (68.2)
Numbness	162 (46.4)	187 (53.6)
Itching	66 (18.9)	283 (81.1)
Is the pain located in an area where the physical examination may reveal one or more of the following characteristics?		
Hypoesthesia to touch	45 (12.9)	304 (87.1)
Hypoesthesia to pinprick	38 (10.9)	311 (89.1)
In the painful area, can the pain be caused or increased by: Brushing?	16 (4.6)	333 (95.4)

Table 4: Factors associated with painful peripheral neuropathy: Bivariate analysis

	Painful diabetic peripheral neuropathy		*P**
	No (*n*=233), *n* (%)	Yes (*n*=116), *n* (%)	
Age (years)			
25-35 (*n*=5)	4 (80.0)	1 (20.0)	0.181
36-45 (*n*=42)	31 (73.8)	11 (26.2)	
46-55 (*n*=114)	82 (71.9)	32 (28.1)	
>55 (*n*=188)	116 (61.7)	72 (38.3)	
Gender			
Male (*n*=152)	116 (76.3)	36 (23.7)	0.001
Female (*n*=197)	117 (59.4)	80 (40.6)	
Educational level (*n*=348)			
Illiterate (*n*=116)	94 (58.4)	67 (41.6)	0.007
Elementary school (*n*=72)	55 (76.4)	17 (23.6)	
Intermediate school (*n*=42)	34 (81.0)	8 (19.0)	
High-school (*n*=46)	28 (60.9)	18 (39.1)	
University/above (*n*=27)	21 (77.8)	6 (22.2)	
Body mass index (*n*=343)			
Normal (*n*=36)	20 (55.6)	16 (44.4)	0.001
Overweight (*n*=121)	97 (80.2)	24 (19.8)	
Obese (*n*=186)	113 (60.8)	73 (39.2)	
Duration of diabetes (years)			
<5 (*n*=86)	65 (75.6)	21 (24.4)	<0.001
5-10 (*n*=107)	87 (81.3)	20 (18.7)	
11-15 (*n*=55)	31 (56.4)	24 (43.6)	
>15 (*n*=95)	47 (49.5)	48 (50.5)	
Glycated hemoglobin (%) (*n*=342)			
<7 (*n*=91)	69 (75.8)	22 (24.2)	0.212
7-8 (*n*=95)	64 (67.4)	31 (32.6)	
8.1-9.5 (*n*=75)	46 (61.3)	29 (38.7)	
>9.5 (*n*=76)	49 (64.5)	27 (35.5)	
Medication for diabetes (*n*=348)			
None (*n*=6)	6 (100)	0 (0.0)	<0.001
Oral hypoglycemic (*n*=191)	146 (76.4)	45 (23.6)	
Insulin (*n*=34)	15 (44.1)	19 (55.9)	
Oral hypoglycemic and insulin (*n*=111)	63 (56.8)	48 (43.2)	

*Pearson Chi-square

rate of PDPN (44.4%), whereas overweight participants had the lowest rate (19.8%), $P = 0.001$. More than half (50.5%) of patients whose duration of diabetes exceeded 15 years compared to 18.7% of those whose duration of diabetes ranged between 5 and 10 years had PDPN ($P < 0.001$). More than half of patients treated with insulin (55.9%) compared to those without treatment and 23.6% of those treated with only oral hypoglycemic drugs had PDPN, ($P < 0.001$) [Table 4].

Multivariate logistic regression analysis revealed that after controlling for confounding effect, females were at higher risk to develop PDPN compared to males (adjusted odds ratio ["AOR"]: 1.96; 95% confidence interval [CI]: 1.09–3.50, $P = 0.024$). Compared to patients whose duration of diabetes was <5 years, those with duration exceeded 15 years were over double risk to have PDPN (AOR: 2.26; 95% CI: 1.04–4.93, $P = 0.039$). Considering patients who did not take treatment as a reference category, those treated either insulin alone or a combination of insulin and oral hypoglycemic were more likely to develop PDPN (AOR: 2.33; 95% CI: 1.59–3.42, $P = 0.010$ and AOR: 1.78; 95% CI: 1.51–2.09, $P = 0.034$, respectively). Patients' educational level and BMI were not significantly associated with the development of PDPN. The results are on display in [Table 5].

As illustrated in Table 6, both physical and MCs of QOL scores were significantly higher in diabetic patients without PDPN compared to those with it; 49.57 ± 9.31 versus 40.77 ± 8.14 for PC QOL and 51.72 ± 9.36 versus 44.35 ± 8.12 for MC QOL, $P < 0.001$.

Table 5: Predictors of painful diabetic peripheral neuropathy: Results of multivariate logistic regression analysis

	Adjusted OR	95% CI	*P*
Gender			
Male (*n*=152)[a]	1.0	-	
Female (*n*=197)	1.96	1.09-3.50	0.024
Duration of diabetes (years)			
<5 (*n*=86)[a]	1.0	-	
5-10 (*n*=107)	0.61	0.45-2.03	0.202
11-15 (*n*=55)	1.99	0.87-4.56	0.104
>15 (*n*=95)	2.26	1.04-4.93	0.039
Medication for diabetes (*n*=348)			
None (*n*=6)	1.0	-	
Oral hypoglycemic (*n*=191)	1.13	0.91-2.42	0.171
Insulin (*n*=34)	2.33	1.59-3.42	0.010
Oral hypoglycemic and insulin (*n*=111)	1.78	1.51-2.09	0.034

[a]Reference category. OR: Odds ratio, CI: Confidence interval

Table 6: Quality of life among diabetic patients, according to the presence of painful diabetic neuropathy

	Mean±SD		*P*
	Patients without PDPN	Patients with PDPN	
PC QOL	49.57±9.31	40.77±8.14	<0.001
MC QOL	51.72±9.36	44.35±8.12	<0.001

SD: Standard deviation; QOL: Quality of life, PDPN: Painful diabetic peripheral neuropathy, PC: Physical component, MC: Mental component

Discussion

The present study is considered the first in the western region of KSA to explore PDPN frequency and associated factors, uncovered prevalence of PDPN among Type 2 diabetic patients was 33.2%; consistent with the 35% and 37.1% figures reported in recent studies from Riyadh,[14] and collective Gulf states;[19] but well below the 65.3% rate reported in earlier Saudi studies.[8] This is clearly an artifact of using different diagnostic tools in detection of PDPN. International surveys suffered same difficulty as USA PDPN prevalence rates ranged between 11% and 25%,[28] whereas UK rates were in the region of 33%.[29] Substantial heterogeneity was noted in the consequence of utilizing different tools to diagnose PDPN as well as variation in the characteristics of samples, methodology of studies, and inclusion criteria.[30]

One important key fining in or study is that female gender, DM duration, and treatment with either insulin alone or in combination with oral hypoglycemic were, collectively, the factors that exerted significant impact on PDNP. Both educational level and BMI, although significant in the unadjusted analysis, were not associated with PDNP at the multivariate level analysis. Our results tally well with regional and international studies as the longer duration of diabetes increase PDNP susceptibility.[8,20,31-35]

Our results, in agreement with previous research findings,[14] insulin therapy was an independent risk factor for PDPN. This could well reflect the severity of the disease and poor glycemic control. The finding that females were at higher risk for PDPN was also observed by others[9,21] and could be attributed to the more sedentary life and higher BMI compared to males.

In our current study, both physical and MCs of QOL scores were lower in diabetic patients with PDPN. The same has been observed in studies carried out in Spain,[22] Belgium,[9] USA,[36] Greece,[37] and France,[24] utilizing the same tool used in the present study (HRQoL-SF12). This deterioration in both physical and MCs of QOL is mostly attributed to adverse effects of the disease on patients such as limited daily activities, erectile dysfunction, pain sensation, and poor quality of sleep. Therefore, there is a need to regularly evaluate the HRQoL of diabetic patients with peripheral neuropathy.[36,38]

This current study has several strengths that addressed past researchers' shortcomings. First, we used DN4; a notoriously reliable, valid, and easily to use diagnostic tool for PDPN. Second, we utilized a reliable and valid tool to assess physical and MCs of QoL in diabetic patients (namely, SF-12). Third, our patients were carefully recruited from primary health-care centers, to represent the overall population of diabetic patients usually seen by family physicians. The results of our study are relevant to family physicians who manage the majority of patients with diabetes in the community. Fourth, we applied robust statistical method to compare with PDNP patients with diabetic patients without peripheral neuropathy to identify and qualitatively evaluate potential risk factors. However, the study has a range of limitations that need to be taken onboard before generalizing its results. We did not include some of the important risk factors that could affect the development of PDPN such as hypertension and lipid profile, particularly triglyceride and cholesterol. Moreover, full neurological examination was not performed to confirm the diagnosis. Furthermore, our investigation evaluated the point

prevalence, given its cross-sectional nature. Future research should employ a longitudinal design, with huge sample sizes, and preferably, big data and machine learning methods.

Conclusion

We summarize the key points as follows:

1. PDNP affects almost a third of DM patients in Western Saudi Arabia
2. Female patients, those with longer duration of the disease and treated with either insulin alone or a combination of insulin and oral hypoglycemic were more likely to have PNDP
3. PNDP negatively impacts both physical and MCs of the QOL of affected DM patients
4. Training should be provided to health-care workers and family physician in terms of identification (by use of DN4), treatment, and prevention of PDPN
5. Regular assessment of QOL of DM patient should be included in any routine clinical encounter
6. Further studies should be more comprehensive in terms of risk factors and larger in scale.

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Conflicts of interest

There are no conflicts of interest.

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