

## Original Research Article

# A cross-sectional study on the quality of life of patients with peripheral diabetic neuropathy pain in Hospital Tegku Ampaun Afzan, Kuantan, Malaysia

Sinan Mohammed Abdullah AL-Mahmood<sup>1\*</sup>, Tariq Abdul Razak<sup>2</sup>, Nik Nur Fatnoon Nik Ahmad<sup>2</sup>, Abdul Hadi Bin Mohamed<sup>2</sup>, Shahrin Tarmizi Bin Che Abdullah<sup>2</sup>

<sup>1</sup>Kulliyah of Nursing, <sup>2</sup>Kulliyah of Medicine, International Islamic University Malaysia, Bandar Indera Mahkota Campus, Jalan Sultan Ahmad Shah, 25200 Kuantan, Pahang Darul Makmur, Malaysia

\*For correspondence: **Email:** [Sinan.almawla@gmail.com](mailto:Sinan.almawla@gmail.com); **Tel:** 06001111002473

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### Abstract

**Purpose:** To evaluate the quality of life of patients with peripheral diabetic neuropathy pain (PDNP) in Hospital Tegku Ampaun Afzan (HTAA), Kuantan, Malaysia.

**Methods:** Ninety (90) participants were selected from the Medical Outpatient Department (MOPD) clinic of HTAA. The study adopted a cross-sectional design, and the self-administered Douleur Neuropathy 4 (DN4) and Audit of Diabetes-Dependent Quality of Life (ADDQoL) questionnaires were used for data collection.

**Results:** The negative impact of diabetes on QoL was clearly reflected in the fact that every domain had a negative mean value. Overall, 27.8 % of the participants reported that DM negatively affected their QoL and 37.8 % expressed the opinion that their QoL would have been higher if they were not diabetic. QoL correlated with marital status and age, with married participants and participants in the age range 50 - 59 years old showing QoL negatively affected ( $p < 0.05$ ) by DM with PDNP. Apart from diabetes type, all other characteristics significantly affected participants QoL as reflected by the various related domains ( $p < 0.05$ ).

**Conclusion:** Based on the findings of this study, it seems that individuals with diabetes and PDNP have a low QoL, with regard to "freedom to eat", "freedom to drink", "physical health", "family life", and "living condition".

**Keywords:** Quality of life, Diabetes, Peripheral neuropathy pain

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## INTRODUCTION

Diabetes mellitus (DM) is one of the diseases with greater impact on public health, not only because of its high prevalence, but, above all, by

the consequences of the chronic complications arising from this disease [1]. In 2017, the number of adults diagnosed with DM at global level was 425 million, according to the International Diabetes Federation (IDF) [2]. If no measures are

adopted to deal with this situation, this figure is expected to rise to 642 million by 2040 [2]. Around 30 % of hospitalised DM patients and 25 % of DM outpatients develop this condition [3]. Clinically, diabetic neuropathy (DN) manifests differently at somatic, autonomic and central levels and has a massive impact on quality of life as well as life expectancy [4]. According to the World Health Organisation (WHO), the manner in which people perceive their life condition within the cultural and value systems that they are living in and in relation to their aims, expectations, standards and worries is referred to as quality of life (QoL) [5]. An essential outcome of diabetes care, QoL is measured via the Audit of Diabetes-Dependent Quality of Life (ADDQoL) tool, which aims to determine how patients perceive that their QoL has been affected by diabetes [6]. Besides being a key outcome on its own, QoL is also a key outcome due to its implications for patients' ability to take care of themselves, which in turns affects how their diabetes is controlled and managed [7]. Knowledge about the QoL of individuals suffering from peripheral diabetic neuropathy pain (PDNP) is lacking, even though this aspect is clearly highly important. The relevant practitioners may assess how severe the disease is and how far along it advanced, but an incompatibility may occur between their perspective on patients' QoL and patients' perception of their QoL [8]. This is why patients' psychological state must be considered when inspecting QoL self-assessments [9]. Therefore, the present study seeks to assess the QoL of PDNP patients.

## METHODS

### Setting and participants

To achieve the aim of quantifying the QoL of PDNP patients, the study adopted a cross-sectional design, and the self-administered DN4 and ADDQoL questionnaires were used for data collection. The location from which Ninety (90) participants were selected was the Medical Outpatient Department (MOPD) clinic of Hospital Tegu Ampaun Afzan (HTAA), Kuantan, Pahang, Malaysia. To be included in the study, participants had to be 18 years of age or older, received a DM diagnosis for over a year, and could read and write in English or Malay. Participants were not included if they suffered from a mental condition, like mental disorder, dementia, and Alzheimer's disease, or neuropathic pain caused by other diseases. Furthermore, to confirm that the pain was due to DN, the participants had to exhibit four symptoms from the DN4 questionnaire, namely, burning, painful coldness, electric shock-like pain and

painless symptoms like numbness, tingling, itching, and pins-and-needles.

Alongside the questionnaires, an information sheet was provided to all participants to inform them about the research goals. The questionnaires were distributed both in English and Malay, and the participants were requested to fill them out by themselves. No deadline for questionnaire completion was set. Participants were asked to sign an informed consent form (ICF) to confirm their agreement to take part and they were also offered the chance to pose any questions that they might have had. Besides the information derived from the two questionnaires, additional information regarding sociodemographic details and disease characteristics (e.g. type, duration, prescribed drugs) was obtained during interviews with the participants conducted as they waited to be consulted by the specialist.

### Ethical consideration

The study was approved by the IIUM Research Ethics Committee (IREC-234), Ministry of Health of Malaysia (NMRR-14-188-19549), and followed the International Compilation of Human Research Standards [10]. As previously mentioned, the researcher informed the participants about the study goals and a consent form was distributed with the questionnaires. The information the participants provided in the questionnaires was kept confidential and only the collected data were processed. The data were not used for any other purpose, academic or otherwise, apart from the stated research aims.

### Instrument

The ten items in the Douleur Neuropathy 4 (DN4) questionnaire were addressed by four questions; more specifically, seven of the item pertained to pain characterisation (e.g. burning, painful cold, electric shocks) and related unusual sensations (e.g., tingling, pins and needles, numbness, itching), while the remaining three items pertained to a succinct bedside neurological examination of the zone where pain occurred, which involved touch hypoaesthesia using a soft brush, pinprick hypoaesthesia using disposable examination pins, and tactile dynamic allodynia using a soft brush. Depending on whether they were positive or negative, items were scored 1 or 0, with the overall possible score being in the range 0-10. An overall score of 4 was established as the cut-off value for PDNP [11].

There are two general items that make up the ADDQoL questionnaire, namely, one item measuring QoL on the whole and another item

consisting of 19 subitems intended to determine how particular facets of life are affected by diabetes. These facets of life include, work life, recreational activities, holidays, local or long-distance trips, physical health, family life, ambitions, friendships and social relationships, close personal relationships, sex life, physical appearance, self-confidence, living conditions, others' reactions, outlook on the future, financial status, reliance on others, and freedom to eat and to drink. In essence, the purpose of these 19 domains is to help the patients provide an assessment of their life and what would it be like if they were free from diabetes.

The impact rating for these domains and importance rating for perceived importance are in the range of -3 to +1 and 0 to +3, respectively. The two ratings are multiplied to obtain a weighted score for every domain, which could be in the range of - 9 to +3. The lower the score, the poorer the QoL is. This is followed by the calculation of a mean weighted impact score (ADDQoL score) for the whole scale across all the domains of pertinence [12]. An earlier study has evaluated how valid and reliable the ADDQoL was, producing values of Cronbach's alpha of 0.945 for the Malay version and 0.907 for the English version [13].

**Sample size**

The Sample size was calculated using Eq 1.

$$n = (Z^2 \times P(1 - P)) / e^2 \dots\dots\dots (1)$$

where Z = value from standard normal distribution corresponding to desired confidence level (Z = 1.96 for 95 % CI), P is expected exact proportion, e is desired precision (half desired CI width). An additional 10 % was added to the total sample for the possibility of incomplete questionnaires. The total sample size for our study based on these criteria required 85 (77 plus 8) [14].

**Statistical analysis**

The results were expressed as percentages and frequencies for categorical variables or by mean values and standard deviation for continuous variables. Independent samples t-test and one-way ANOVA were used to examine the differences in overall QoL and its domains regarding demographic variables and disease-related data. SPSS software version 20.0 (SPSS Inc, Chicago, IL, USA) was used for all data analysis. P < 0.05 was considered significant in all the tests.

**RESULTS**

**Demographic characteristics of study participants**

Table 1 shows the sociodemographic and clinical features of the diabetics with PDNP included in this study. According to the results of the sociodemographic data analysis, most participants were male (60 %) in the age range 60 - 69 years old (51.1 %), who were married (92.2 %), out of work (4.4 %) and with an average financial status (51.1 %). Regarding clinical characteristics, most participants had type 1 diabetes mellitus (T1DM) (64.4 %) and had received their diagnosis a decade or more ago (44.4 %). Furthermore, 41 of the 90 participants received solely insulin-based treatment (45.6 %), 32 were prescribed oral hypoglycemic agents (35.6 %), and 17 received a mixture of the other two treatment approaches (18.9 %).

**Table 1:** Socio-demographic and clinical characteristics of PDNP

<b>Variables</b>	<b>N=90</b>	<b>%</b>
<b>Gender</b>	54	60
Male	36	40
Female		
<b>Age group (yr)</b>		
<50	13	14.4
50-59	23	25.6
60-69	46	51.1
>69	8	8.9
<b>Occupation</b>		
Unemployed	50	55.6
Employed	40	44.4
<b>Marital status</b>		
Married	83	92.2
Single	7	7.8
<b>Economic status</b>		
Poor	28	31.1
Moderate	46	51.1
Good	16	17.8
<b>Type of diabetes</b>		
Type I	58	64.4
Type II	32	35.6
<b>Duration of diabetes</b>		
1-4 years	19	21.1
5-9 years	31	34.4
≥10 years	40	44.4
<b>Type of medication</b>		
OHA only	32	35.6
Insulin only	41	45.6
Combination (biguanide+insulin)	17	18.9

**Impact of diabetes on QoL domains**

The negative impact of diabetes on QoL was clearly reflected in the fact that every domain had a negative mean value. Overall, 27.8 % of the

participants reported that DM negatively affected their QoL and 37.8 % expressed the opinion that their QoL would have been higher if they had not been diabetics. Table 2 indicates how the answers were distributed and the weights allocated to the impact ratings. The domains most affected by DM with PDNP were “freedom to eat” (mean impact rating:  $-2.74 \pm 0.53$ ), “freedom to drink” (mean impact rating:  $-2.70 \pm 0.46$ ), “physical health” (mean impact rating:  $-2.49 \pm 0.92$ ), “family life” (mean impact rating:  $-2.24 \pm 1.17$ ) and “living condition” (mean impact rating:  $-2.22 \pm 1.03$ ). By contrast, the domains least affected by DM were “holidays” (mean impact rating:  $-0.83 \pm 1.26$ ), “physical appearance” (mean impact rating:  $-0.96 \pm 1.23$ ), “working life” (mean impact rating:  $-1.12 \pm 1.135$ ), “people’s reaction” (mean impact rating:  $-1.27 \pm 1.17$ ) and “sex life” (mean impact rating:  $-1.32 \pm 1.18$ ). Furthermore, the domains that the participants attributed the greatest and lowest importance were respectively “freedom to eat” (mean  $2.87 \pm 0.34$ ) and “dependence on others” (mean  $0.11 \pm 0.31$ ). These two domains were

also found to be the QoL domains impacted to the greatest and least degree by DM, with mean  $-7.95 \pm 1.94$  for “freedom to eat” and mean  $-0.27 \pm 0.84$  for “dependence on others”.

### Impact of sociodemographic and clinical features on overall QoL score

Table 3 presents the results obtained regarding discrepancies in the overall QoL and its domains associated with demographic and clinical variables. According to the results of the independent t-test and one-way ANOVA, QoL was found to be correlated with marital status and age; thus, married participants and participants in the age range 50 - 59 years old had their QoL significantly ( $p < 0.05$ ) negatively affected by DM with PDNP. By contrast, QoL was not observed to be statistically significantly correlated with gender, occupation, economic status, diabetes type or duration, and medication type ( $p > 0.05$ ).

**Table 2:** Distribution of responses (N = 90) by impact and importance rating together with weighted impact score

Q	Domain	Impact rating		Importance rating		Weighted impact score	
		mean± SD	(range)	mean± SD	(range)	mean± SD	(range)
1	Leisure activities	-1.94±1.14	(-3_0)	1.91±1.21	(-3_3)	-4.73±3.71	(-9_3)
2	Working life	-1.12±1.35	(-3_0)	1.22±1.40	(0_3)	-3.12±4.02	(-9_0)
3	Journeys	-1.99±1.40	(-3_3)	2.51±0.76	(0_3)	-5.51±4.03	(-9_6)
4	Holidays	-0.83±1.26	(-3_0)	0.89±1.29	(0_3)	-2.14±3.71	(-9_0)
5	<b>Physical health</b>	<b>-2.49±0.92</b>	(-3_0)	2.63±0.77	(0_3)	<b>-7.03±2.90</b>	(-9_0)
6	<b>Family life</b>	<b>-2.24±1.17</b>	(-3_3)	2.54±0.85	(0_3)	<b>-6.17±3.43</b>	(-9_0)
7	Friendship and social life	-1.76±1.11	(-3_0)	1.64±1.06	(0_3)	-3.73±3.37	(-9_0)
8	Personal relationship	-1.48±1.14	(-3_0)	1.67±1.02	(0_3)	-3.45±3.47	(-9_0)
9	Sex life	-1.32±1.18	(-3_3)	1.44±0.86	(0_3)	-2.47±2.99	(-9_6)
10	Physical appearance	-0.96±1.23	(-3_0)	1.36±1.23	(0_3)	-2.21±3.35	(-9_0)
11	Self-confidence	-1.49±1.15	(-3_0)	1.61±1.12	(0_3)	-3.22±3.50	(-9_0)
12	Motivation	-1.38±1.23	(-3_3)	1.54±1.12	(0_3)	-2.98±3.33	(-9_0)
13	People’s reaction	-1.27±1.17	(-3_0)	1.37±1.08	(0_3)	-2.63±3.39	(-9_0)
14	Feeling about future	-1.79±1.17	(-3_0)	1.62±1.16	(0_3)	-3.85±3.54	(-9_0)
15	Financial situation	-1.83±1.16	(-3_0)	2.04±1.14	(0_3)	-4.31±3.80	(-9_0)
16	<b>Living condition</b>	<b>-2.22± 1.03</b>	(-3_0)	2.51±0.83	(0_3)	<b>-6.05±3.40</b>	(-9_0)
17	Dependence on others	-1.88± 1.21	(-3_0)	<b>0.11±0.31</b>	(0_3)	-0.27±0.84	(-3_0)
18	<b>Freedom to eat</b>	<b>-2.74±0.53</b>	(-3_0)	<b>2.87±0.34</b>	(2_3)	<b>-7.95±1.94</b>	(-9_0)
19	<b>Freedom to drink</b>	<b>-2.70±0.46</b>	(-3_-2)	2.73±0.46	(1_3)	<b>-7.47±2.04</b>	(-9_-2)

**Table 3:** Average weighted impact scores by socio-demographic and clinical characteristics of diabetic patients with PDNP

Variable	Average weighted impact score	
	Mean $\pm$ SD	P-value
<b>Gender</b>		0.814
Male	-4.13 $\pm$ 1.77	
Female	-4.24 $\pm$ 2.25	
<b>Age group (yr)</b>		<b>0.017</b>
<50	-4.15 $\pm$ 1.28	
<b>50-59</b>	<b>-4.94<math>\pm</math> 2.22*</b>	
60-69	-4.10 $\pm$ 1.97	
>69	-2.43 $\pm$ 0.73	
<b>Occupation</b>		0.903
Unemployed	-4.20 $\pm$ 2.16	
Employed	-4.15 $\pm$ 1.72	
<b>Marital status</b>		<b>0.000</b>
<b>Married</b>	<b>-4.28<math>\pm</math> 2.00*</b>	
Single	-2.89 $\pm$ 0.62	
<b>Economic status</b>		0.122
Poor	-3.95 $\pm$ 1.52	
Moderate	-3.99 $\pm$ 2.00	
Good	-5.09 $\pm$ 2.37	
<b>Type of diabetes</b>		0.171
Type I	-4.39 $\pm$ 1.95	
Type II	-3.79 $\pm$ 1.96	
<b>Duration of diabetes</b>		0.157
1-4 years	-4.04 $\pm$ 1.61	
5-9 years	-4.71 $\pm$ 2.15	
$\geq$ 10 years	-3.82 $\pm$ 1.92	
<b>Type of medication</b>		0.067
OHA only	-3.79 $\pm$ 1.96	
Insulin only	-4.69 $\pm$ 2.04	
Combination (biguanide+insulin)	-3.64 $\pm$ 1.54	

### Impact of sociodemographic and clinical features on QoL domains

Table 4 lists the average weighted impact scores associated with participants' sociodemographic and clinical characteristics (i.e., gender, age group, occupation, marital status, economic status, diabetes type and duration, and type of medication). Apart from diabetes type, all other characteristics significantly affected participants QoL as reflected by the various related domains ( $p < 0.05$ ).

## DISCUSSION

Overall, the results of the ADDQoL questionnaire revealed that every domain related to participants' QoL was adversely affected by diabetes. As far as the researcher is aware, no other study has addressed the QoL of individuals with diabetes and PDNP in Malaysia. To determine the QoL of these individuals, the study investigated their sociodemographic and clinical features, and found that the participants' QoL

was low-to-moderate, according to the mean score of the overall QoL and related domains. The study employed the popular tool of ADDQoL questionnaire to gain a comprehensive understanding of QoL among individuals with diabetes [12,13,15].

The findings revealed that the QoL domain of "freedom to eat" was adversely affected by diabetes to the highest degree, reflecting the major impact of diet limitations on QoL. This corroborated the results of previous studies [16,17]. Furthermore, diabetes with PDNP also had a significant negative effect on the QoL domain "freedom to drink". By contrast, the lowest impact of diabetes was recorded in the case of the "holiday" domain. This was inconsistent with the findings of earlier studies [13,15], which reported that the domains least impacted were "people's reaction" and "working life".

Solely age and marital status out of participants' sociodemographic and clinical features were found to significantly impact QoL, as indicated by the average weighted impact scores. Individuals with ages between 50 and 59 years old were more likely to experience a lower QoL. This was consistent with the findings of two other studies [18,19], which reported a direct correlation between younger age and lower ADDQoL scores as well as a more extensive adverse effect on QoL among individuals with diabetes. This paradox may be due to the fact that, unlike older diabetics, younger diabetics are more anxious about their future and the implications of their disease for their life [12]. In addition, a close correlation between marital status and poorer QoL was also observed in the present study. This was inconsistent with the result of a previous study [18], which did not find a significant correlation between marital status and lower ADDQoL scores. The reason for this might be due to the fact that diabetics' sexual activity might be diminished by PDN.

Many of the 19 domains in the ADDQoL questionnaire were significantly affected by the participants' sociodemographic and disease features. However, among the two genders, a higher QoL was registered in the case of male participants. Indeed, the "living condition" domain was significantly impacted by the variable of male gender, while the "motivation", "people's reaction" and "feeling about future" domains were significantly impacted by the variable of female gender. Other studies also reported that male diabetics enjoyed a better QoL compared to female diabetics [20].

**Table 4:** Impact of socio-demographic and clinical characteristics on individual life domains

Item of significance	Variable (mean ± SD)				P-value
	<b>Gender</b>				
	<i>Male</i>		<i>Female</i>		
Motivation	-2.35±3.06		-3.94±3.53*		0.031
People's reaction	-1.94±3.04		-3.66±3.66*		0.023
Feeling about future	-3.25±3.65		-4.75±3.22*		0.045
Living condition	-6.74±3.10*		-5.02±3.61		0.023
	<b>Age group (yr)</b>				
	< 50	50-59	60-69	>69	
Holidays	-0.07±0.277	-3.26±4.23*	-2.54±3.94	-	0.023
Friendship and social life	-3.92±3.49	-5.69±3.67*	-3.17±2.92	-1.00±1.85	0.002
Personal relationship	-2.00±3.16	-5.78±3.55*	-3.13±3.14	-1.00±1.85	0.000
Sex life	-1.76±3.32	-3.86±2.75*	-2.39±2.99	-0.12± 0.35	0.012
Physical appearance	-2.53±3.23	-3.86±3.59*	-1.65±3.24	-0.12±0.35	0.015
Self-confidence	-4.30± 3.63	-5.30± 3.87*	-2.34± 2.93	-0.50± 0.75	0.000
Motivation	-4.15±3.78	-4.52±3.57*	-2.39±2.91	-0.12±0.35	0.002
Feeling about future	-5.38±3.37	-6.00±2.71*	-2.97±3.48	-0.25±0.46	0.000
Financial situation	-5.23±3.13*	-4.65±4.16	-4.58±3.75	-0.25±0.70	0.014
	<b>Occupation</b>				
	Unemployed		Employed		
Working life	-1.40± 3.21		-5.27± 3.92*		0.000
Physical appearance	-2.88± 3.67*		-1.37± 2.71*		0.028
Self-confidence	-3.88± 3.69*		-2.40± 3.10		0.042
	<b>Marital status</b>				
	Married		Single		
Friendship and social life	-3.92± 3.41*		-1.42± 1.90		0.012
Personal relationship	-3.62± 3.52*		-1.42± 1.90		0.023
Sex life	-2.63± 3.06*		-0.57± 0.78		0.000
Physical appearance	-2.37± 3.43*		-0.28± 0.48		0.000
Self-confidence	-3.46± 3.53*		-0.28±0.48		0.000
Motivation	-3.21± 3.37*		-0.28±0.48		0.000
People's reaction	-2.83± 3.45*		-0.28±0.48		0.000
Feeling about future	-4.16± 3.51*		-0.14± 0.37		0.000
Financial situation	-4.56± 3.80*		-1.28± 2.21		0.006
Living condition	-5.90±3.45		-7.85± 2.03*		0.048
	<b>Economic status</b>				
	Poor	Moderate	Good		
Working life	-2.92±3.72	-2.47±3.88	-5.31±4.42*		0.049
Living condition	-6.80±3.22	-5.08±3.40	-7.37±2.80*		0.018
Freedom to eat	-7.53±1.95	-8.56±1.32*	-6.93±2.76		0.005
	<b>Duration of diabetes (yr)</b>				
	1-4	5-9	>10		
Leisure activities	-2.78±2.37	-5.12±3.81	-5.35±3.91*		0.034
People's reaction	-2.10±3.03	-4.16±3.88*	-1.70±2.74		0.006
Financial situation	-5.36±3.98*	-5.22±3.59	-3.10±3.60		0.024
	<b>Type of medication</b>				
	OHA only	Insulin only	Combination		
Leisure activities	-3.81±3.47	-5.92±3.43*	-3.58±4.13		0.018
Physical appearance	-1.81±3.12	-3.09±3.67*	-0.82±2.32		0.042
	<b>Type of diabetes</b>				
	Type I		Type II		
All items	-		-		> 0.05

Furthermore, by contrast to participants younger than 60 years of age, those older than 60 years of age had a better social life. Meanwhile, an earlier study revealed that a higher QoL was enjoyed by diabetics younger than 50 years of age [17].

Four of the 19 domains were significantly affect-

ed by the clinical characteristics of diabetes duration and types of medication. More specifically, the domains of "financial situation", "people's reaction", and "leisure activities" were affected by diabetes duration. Conversely, an earlier study [17] reported that it was the "self-confidence", "sexual life" and "holidays" domains that were significantly affected by diabetes

duration. Meanwhile, in the present study, “leisure activities” and “physical appearance” were adversely impacted by insulin treatment.

Again, this result differed from that of earlier studies [21,22], which found that the QoL domains affected by insulin treatment were “family relationships”, “sex life”, “travel”, and “family future”. These inconsistencies between the present study and earlier ones might be due to cultural and context-related aspects, discrepancies in participants’ sociodemographic characteristics, and differences in the assessment tools employed [23].

### Limitations of the study

Generalisation of the study results to the wider population of Kuantan was not possible because data were collected from just one, albeit major, hospital in the city. The study results might also be somewhat distorted by the fact that data were derived from self-reported questionnaires, which present the risk of participants underestimating or exaggerating their health-related QoL.

### CONCLUSION

The findings of this study indicate that individuals with diabetes and PDNP have a low QoL, particularly, with regard to “freedom to eat”, “freedom to drink”, “physical health”, “family life”, and “living condition”. Certain ADDQoL domain scores are adversely impacted by factors such as female sex, younger age, lack of employment, marriage, good financial position, diabetes duration, and insulin-based treatment.

Therefore, not all domains are equally affected by the same sociodemographic and clinical features. This fact must be taken into account to effectively address each patient’s needs. Doctors and healthcare practitioners may find these results useful in formulating effective approaches and strategies for enhancing patients’ QoL. To further reinforce the results, the study should be repeated on a larger scale with a longer follow-up interval. Future studies should also address the management of individuals suffering from PDNP as well as assess the outcomes of different medical interventions.

### DECLARATIONS

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### Conflict of interest

The authors have no conflict of interest to declare with regard to this work.

### Contribution of authors

The authors declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by them. All authors participated in the designing, collecting of data, analysis and writing of this article.

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