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Prevalence of Diabetic Peripheral Neuropathy and Its Association With Vitamin B12 Deficiency and Health-Related Quality of Life

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Abstract

Background: The aim of the study was to determine the prevalence of diabetic peripheral neuropathy and vitamin B12 deficiency, their associated factors, and impact on health-related quality of life in a sample from the Dominican Republic.

Methods: A total of 367 patients with diabetes were recruited. The Toronto Clinical Scoring System (TCSS) was used to evaluate the presence of neuropathy symptoms, while the 36-Item Short Form Health Survey (SF-36) was used to assess health-related quality of life.

Results: Of the participants, 33.5% had neuropathy according to TCSS scores. Only one participant reported having a previous diagnosis of neuropathy. Factors associated with neuropathy were age, chronic renal insufficiency, and history of stroke. The prevalence of vitamin B12 deficiency was 4.5%, and no association was found with neuropathy. The presence of neuropathy significantly affected ($P < 0.05$) all physical dimensions of the SF-36 and the vitality dimension. Factors associated with the Physical Component Score (PCS) were age, neuropathy, and total number of comorbidities; factors associated with Mental Component Score (MCS) were age, sex, and being widowed.

Conclusions: The prevalence of neuropathy was high and its impact on QoL was significant. Almost none of the patients in which neuropathy was detected had a previous diagnosis. Considering this, the development of awareness and prevention interventions among both doctors and patients in the Dominican context is of utmost importance.

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Introduction

Diabetes mellitus (DM) affects between 10% and 14% of the population of the Dominican Republic's population [1-3]. If not properly managed, it can lead to complications such as cardiovascular disease, chronic renal insufficiency, and lower limb amputations [4, 5]. As the disease progresses, it affects individuals severely, both physically and emotionally, requiring more healthcare services and raising its associated costs [6-8].

One of its most common complications is diabetic peripheral neuropathy (DPN). The prevalence of this condition shows high variability depending on the population studied, ranging from 10% to 50% of patients with diabetes [9, 10]. This condition has important implications as it can lead to the development of diabetic foot ulcers and lower limb amputation [11, 12]. Before reaching this stage, it causes symptoms such as pain, loss of sensation, and motor function impairment, which negatively impacts the health-related quality of life (HRQoL) of those affected. Multiple research studies have shown that people with diabetes and DPN report considerably lower levels of quality of life compared to those who only have diabetes [13-15].

Several factors have been associated with the development of DPN, including vitamin B12 deficiency [16, 17]. Several studies have highlighted that vitamin B12 supplementation may be beneficial in the treatment of this condition. Additionally, some trials have reported improvements in quality of life following the administration of vitamin B12 [18, 19]. Nevertheless, there is still no consensus or clear recommendation regarding the use of vitamin B12 in the management of DPN.

There is a lack of data from research studies with solid methodologies that accurately report the prevalence of DPN in the Dominican Republic. Due to its high variability, it is challenging to approximate it from those observed in other populations. Furthermore, there are no concrete data that report how DPN and vitamin B12 deficiency, either individually or in

combination, affect the quality of life of the Dominican population. Therefore, this research study seeks to address this gap in scientific evidence by determining the prevalence of DPN in the Dominican Republic, identifying its associated factors, evaluating its correlation with vitamin B12 deficiency, and assessing how this condition affects the HRQoL of those who have this condition.

Materials and Methods

A cross-sectional study was conducted from July 2024 to January 2025 at three medical centers in the Dominican Republic. They were located in the following provinces: Distrito Nacional, Monte Plata, and San Cristobal.

Study population and sample size

Included participants were patients aged 18 years or older, with a diagnosis of type 2 diabetes mellitus (T2DM) for more than 1 year, who provided informed consent. Patients were excluded if they had any of the following conditions: 1) cognitive disability that impeded answering the questionnaire or provide informed consent; 2) cancer diagnosis or chemotherapy treatment; 3) Diagnosis of any of the following: tuberculosis, human immunodeficiency virus (HIV), herpes, hepatitis C, pernicious anemia, celiac disease, chronic kidney failure stage V or on hemodialysis treatment, peripheral arterial disease, autoimmune inflammatory diseases (lupus, rheumatoid arthritis, Sjogren's syndrome, Guillain-Barre syndrome), connective tissue diseases, spinal diseases (herniated discs, transverse myelitis, etc.), multiple sclerosis, amyotrophic lateral sclerosis, any neurological or rheumatological disease associated with altered sensation, loss of strength, or altered consciousness; 4) history of gastrectomy, gastric bypass surgery, or small intestine surgery; 5) history of psychiatric disorders, including psychotic disorders, suicidal attempts, and current severe major depressive disorder or generalized anxiety disorder; 6) major surgery or hospitalization in the previous month; 7) diagnosis of cerebrovascular accident (CVA) in the previous 6 months, or CVA with sensory or motor sequelae; 8) pregnant women or women who gave birth within the previous 6 months; 9) history of lower extremity fractures in the previous 12 months; 10) presence of an ulcer in the lower extremity that prevents physical evaluation; 11) major lower limb amputation or other physical limitation that prevents physical examination; 12) any functional or physical disability not related to diabetes that significantly limits activities of daily living; 13) consumption of a vegan diet; 14) alcohol use disorder; 15) consumption of vitamin B12 supplements or currently undergoing treatment with vitamin B12; 16) inability to complete the self-reported 36-Item Short Form Health Survey (SF-36) form (e.g., those who are unable to read or write).

A sample size of 385 participants was calculated using a 95% confidence level, a margin of error of 5%, and an estimated prevalence of 50%. A total of 367 patients were recruited, reaching 95.3% of the calculated sample size.

Data collection instruments and measurements

A questionnaire designed by the researchers was used to obtain general and clinical data, as well as information such as the frequency of medical appointments for diabetes and foot evaluations, through participant interviews. Clinical data were also validated and completed through the review of participants' medical records.

For the detection of DPN, the Toronto Clinical Scoring System (TCSS) was used, which has been previously validated for this purpose [20]. According to the TCSS criteria, participants with scores of 6 to 8 were considered as having mild neuropathy, those with scores from 9 to 11 as moderate neuropathy, and those with scores of more than 11 as severe neuropathy.

To assess HRQoL, patients were asked to complete the SF-36 questionnaire. This questionnaire is the most frequently used instrument to measure HRQoL and it has been previously validated for use in patients with diabetes [21]. A license agreement was provided by QualityMetric for the utilization of the SF-36 for this research study.

Lastly, vitamin B12 levels were obtained by reviewing participants' medical records. Only results determined by the quantitative enzyme immunoassay (QEIA) method and measured within the last 6 months prior to participation in the study were considered valid. In cases where no recent valid measurements were found in the participants' record, vitamin B12 measurement was prescribed.

Data analysis

A univariate analysis was performed where qualitative variables were summarized utilizing their frequency and proportion and quantitative variables with their mean and standard deviation (SD) or median and interquartile range (IQR) for non-normal distribution. The normality of distribution of quantitative variables was assessed using the Kolmogorov-Smirnov test.

The prevalence of DPN was calculated by dividing the sum of participants with DPN by the total number of participants and then multiplying the result by 100. To analyze the relationship between qualitative and quantitative variables, *t*-tests or one-way analysis of variance (ANOVA) were used for normally distributed data, while the Kruskal-Wallis or Mann-Whitney U tests were used for non-normal distributed data. The Chi-square test was used to evaluate association between qualitative variables. P-values less than 0.05 were considered significant.

To estimate the strength of correlation between the presence of DPN and sociodemographic and clinical characteristics, and to control for possible confounding factors, a multiple logistic regression model was constructed. Furthermore, multiple linear regression models were created to assess factors associated with the Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores of the SF-36.

Scores of the SF-36 were calculated by using the software provided by QualityMetric for this purpose. All other analyses

Table 1. Sociodemographic Characteristics of the Participants (N = 367)[a]

Variables	No. (%)	Neuropathy (N = 123)	No neuropathy (N = 244)	P value
Sex				
Women	210 (57.2)	55 (44.7)	102 (41.8)	0.674
Men	157 (42.8)	68 (55.3)	142 (58.2)	
Age (years)				0.003*
20 - 45	31 (8.4)	10 (8.1)	21 (8.6)	
46 - 55	53 (14.4)	15 (12.2)	38 (15.6)	
56 - 65	130 (35.4)	35 (28.5)	95 (38.9)	
65 - 75	99 (27.0)	33 (26.8)	66 (27.0)	
> 75	54 (14.7)	30 (24.4)	24 (9.8)	
Marital status				0.39
Married	192 (52.3)	63 (51.2)	129 (52.9)	
Divorced	21 (5.7)	10 (8.1)	11 (4.5)	
Single	59 (16.1)	16 (13.0)	43 (17.6)	
Common-law union	59 (16.1)	19 (15.4)	40 (16.4)	
Widowed	36 (9.8)	15 (12.2)	21 (8.6)	
Educational level				0.639
Postgraduate studies	48 (13.1)	16 (13.1)	32 (13.1)	
None	1 (0.3)	0 (0)	1 (0.41)	
None (can read)	6 (1.6)	4 (3.3)	2 (0.8)	
Primary	63 (17.2)	25 (20.3)	38 (15.6)	
Secondary	91 (24.8)	29 (23.6)	62 (25.4)	
Technical	6 (1.6)	2 (1.6)	4 (1.6)	
University	152 (41.4)	47 (38.2)	105 (43.0)	
Smoker				0.785
Yes	18 (4.9)	5 (4.1)	13 (5.3)	
No	349 (95)	118 (95.9)	231 (94.7)	

[a]Statistical significance was determined using the Chi-square test. *Statistically significant P-values (P values < 0.05).

were performed by using the Python language v. 3.12.4 in the integrated development environment Jupyter Notebook.

Ethical considerations

This research was carried out in accordance to international ethical principles, recommendations of the Declaration of Helsinki, and the International Council for Harmonization. The study protocol was approved by the Research Ethics Committee of the Hospital Dr. Hugo Mendoza and by the Consejo Nacional de Bioetica en Salud (CONABIOS), approval number 038-2024.

Results

A total of 367 patients were recruited. The only variables with missing data were related to laboratory tests. Regarding these, only the following number of participants had reported values for each of the following tests: 248 (67.6%) for glycated hemoglobin (HbA1c), 258 (70.3%) for blood glucose, 230 (62.7%) for total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), and triglycerides, 220 (59.9%) for complete blood count, 209 (56.9%) for creatinine, 138 (37.6%) for thyroid-stimulating hormone (TSH), and only 21 (5.7%) for folic acid.

A total of 14 participants did not report vitamin B12 measurements and were lost in follow-up. Due to the small volume of unreported data (< 10%) and the random nature of the absent information, the 14 missing values were estimated by using the K-nearest neighbor algorithm, completing 100% of the vitamin B12 values for all participants.

Demographic characteristics of participants

Demographic characteristics of the sample are shown in Table 1. Most of the participants were females (n = 210, 57.2%) with an average age of 63 (SD 11.8) years. When comparing these

Table 2. Clinical Characteristics of the Participants (N = 367)[a]

Variables	Total (N = 367)	Neuropathy (N = 123)	No neuropathy (N = 244)	P-value
Time with diabetes (years)	12.0 (9.5)	14.8 (10.1)	10.6 (8.8)	< 0.001*
Treatment for diabetes				
Oral antidiabetics	329 (89.6)	98 (79.7)	231 (94.7)	< 0.001*
Insulin	113 (30.8)	59 (48)	54 (22.1)	< 0.001*
Injectables	9 (2.5)	5 (4.1)	4 (1.6)	0.289
Diet and exercise	70 (19.1)	12 (9.8)	58 (23.8)	0.002*
Others	3 (0.8)	1 (0.8)	2 (0.8)	0.727
Metformin	282 (76.8)	85 (69.1)	197 (80.7)	0.018*
Comorbidities				
Hypertension	284 (77.4)	101 (82.1)	183 (75.0)	0.16
Dyslipidemia	128 (34.9)	51 (41.5)	77 (31.6)	0.078
Chronic kidney disease	6 (1.6)	5 (4.1)	1 (0.4)	0.03*
Obesity	65 (17.7)	19 (15.4)	46 (18.9)	0.508
Cerebrovascular accident	12 (3.3)	8 (6.5)	4 (1.6)	0.035*
Acute myocardial infarction	7 (1.9)	5 (4.1)	2 (0.8)	0.081
Heart failure	3 (0.8)	2 (1.6)	1 (0.4)	0.543
Neuropathy	3 (0.8)	1 (0.8)	2 (0.8)	0.544
Retinopathy	8 (2.2)	6 (4.9)	2 (0.8)	0.033*
Others	138 (37.6)	42 (34.1)	96 (39.3)	0.045
Frequency of diabetes checkup visits (per year)	2.8 (1.5)	2.9 (1.7)	2.8 (1.4)	0.746
Frequency of foot evaluations (per year)	0.3 (1.2)	0.5 (1.9)	0.3 (0.6)	0.285
Metabolic parameters				
Glycated hemoglobin	7.7 (1.91)	8.3 (2.1)	7.4 (1.8)	< 0.001*
Fasting glucose	142.6 (54.7)	158.4 (68.7)	133.4 (42.3)	0.003*
Total cholesterol	184.6 (47.8)	186.1 (48.1)	183.7 (47.7)	0.716
HDL cholesterol	48.3 (14.4)	47.0 (16.1)	48.9 (13.5)	0.105
LDL cholesterol	110.0 (41.6)	111.0 (40.8)	109.2 (42.1)	0.791
Triglycerides	141.4 (83.2)	149.2 (69.6)	137.2 (89.7)	0.101
Creatinine	1.0 (0.5)	1.1 (0.6)	0.89 (0.31)	0.034*
Vitamin B12	527.6 (318.4)	575.6 (355.7)	503.4 (295.6)	0.035*
TSH	2.4 (1.7)	2.3 (1.4)	2.5 (1.78)	0.615
Folic acid	18.0 (5.7)	17.6 (4.9)	18.5 (6.3)	0.749
Hemoglobin	13.4 (1.4)	13.1 (1.3)	13.5 (1.5)	0.011*
BMI	29.5 (5.2)	29.1 (5.0)	29.6 (5.4)	0.468
Systolic blood pressure	130 (25)	135 (30)	130 (20)	0.027*
Diastolic blood pressure	80 (10)	80 (10)	80 (15)	0.392

[a]Quantitative variables are expressed as mean (standard deviation) or median (interquartile range), and qualitative variables as frequency (percentage). Statistical significance was determined using Student's *t*-test, Mann-Whitney U, and Chi-square test. *Statistically significant P-values (P values < 0.05). BMI: body mass index; HDL: high-density lipoprotein; LDL: low-density lipoprotein; TSH: thyroid-stimulating hormone.

variables between participants that presented DPN and those that did not, statistically significant differences were found by age with the DPN group being older (P = 0.003).

Clinical characteristics of participants

Clinical characteristics of the sample are shown in Table 2. According to the TCSS scores, at the moment of the examination, 33.5% (n = 367, 95% confidence interval (CI): 28.9-38.5%) of participants had scores that indicate the presence of DPN. This neuropathy was classified as mild in 17.2% (95% CI: 13.7-21.4%), moderate in 9.3% (95% CI: 6.7-12.7%), and severe in 7.1% (95% CI: 4.9-10.2%) of participants. Among all participants who showed signs of neuropathy, only one reported DPN as a previously known comorbidity. In con-

trast, two participants who reported having neuropathy were classified as not having signs of neuropathy according to the TCSS.

The mean duration of diabetes was 12 (SD 9.5) years. Furthermore, participants reported on average having 2.8 (SD 1.5) annual medical consultations to follow-up on their diabetes, while the average number of reported foot examinations per year was 0.3 (SD 1.2). The most frequently reported treatment for diabetes was oral antidiabetics, reported by 89.6% of participants, with 76.8% reporting metformin use. Only 30.8% of participants reported using insulin.

Participants with DPN had statistically significant longer duration of diabetes (14.8 ± 10.1 vs. 10.6 ± 8.8 years, P < 0.001) and higher prevalence of insulin use (48% vs. 22.1%, P < 0.001). Moreover, those with DPN presented statistically higher values of HbA1c (8.3±1.9% vs. 7.4±1.8%, P < 0.001), fasting glucose (158.4 ± 68.7 vs. 133.4 ± 42.3, P = 0.003), vitamin B12 (575.6 ± 355.7 vs. 503.4 ± 295.6, P = 0.035), and systolic blood pressure (135 ± 35 vs. 130 ± 20, P = 0.027).

The prevalence of vitamin B12 deficiency was 4.5% (95% CI: 2.7-7%). However, no association was found between this deficiency and the presence of DPN (P > 0.05). On the other hand, significant differences were found in B12 levels between participants who used and did not use metformin, with higher levels observed in those who did not use it (583.9 ± 297.3 vs. 510.6 ± 323.0, P = 0.008). Additionally, all participants who presented vitamin B12 deficiency reported using metformin (P = 0.029).

Factors associated with the presence of diabetic neuropathy

The results of the logistic regression model are shown in Table 3. The model shows that the variables that remained significantly associated with the presence of DPN were age (odds ratio (OR): 1.02, 95% CI: 1.006 - 1.048), chronic kidney disease (CKD) (OR: 10.39, 95% CI: 1.14 - 95.03), and CVA (OR: 3.55, 95% CI: 1.02 - 12.39).

Table 3. Logistic Regression Model for the Presence of Diabetic Peripheral Neuropathy

	OR (95% CI)	P-value
Dependent variable		
Diabetic peripheral neuropathy		
Independent variables		
Sex	1.14 (0.71, 1.81)	0.587
Age	1.03 (1.01, 1.05)	0.009*
Vitamin B12 deficiency	0.31 (0.07, 1.42)	0.131
Metformin	0.73 (0.43, 1.25)	0.248
Chronic kidney disease	10.4 (1.14, 95.03)	0.038*
Diabetic retinopathy	5.05 (0.96, 26.54)	0.056
Dyslipidemia	1.59 (0.99, 2.56)	0.057
Stroke	3.55 (1.02, 12.39)	0.047*

*Statistically significant P-values (P values < 0.05). CI: confidence interval; OR: odds ratio.

HRQoL

Table 4 shows the SF-36 scores for all its dimensions of HrQoL. In general, the lowest score was seen in both the PCS and MCS scores, while the social function dimension had the highest score. In general, patients with DPN had significantly lower scores in all dimensions related to physical health (PCS, physical functioning, physical role limitations, bodily pain, general health, P < 0.05) and also in the vitality dimension (P = 0.003).

Results of multiple linear regression models for each summary score of the SF-36 are shown in Table 5. Being of the male sex was the only variable that had a positive correlation with a higher PCS score (β: 3.6, 95% CI: 1.9 - 5.2). In contrast, the following variables were associated with a lower PCS score: age (β: -0.14, 95% CI: -0.2 to -0.068), total number of comorbidities (β: -1.26, 95% CI: -2.12 to -0.4), and the presence of DPN (β: -5.5, 95% CI: -7.3 to -3.8).

Table 4. SF-36 Scores by Dimension (N = 367)[a]

Variables	Total (N = 367)	Neuropathy (N = 123)	No neuropathy (N = 244)	P-value
PCS	48.6 (8.8)	44.3 (8.9)	50.8 (7.9)	< 0.001*
Physical functioning	78.5 (23.2)	69.3 (25.8)	83.2 (20.4)	< 0.001*
Physical role limitations	71.2 (29.7)	60.4 (32.0)	76.8 (26.9)	< 0.001*
Bodily pain	65.2 (27.3)	56.1 (28.0)	70.0 (25.8)	< 0.001*
General health	64.1 (22.2)	58.2 (25.0)	67.1 (20.1)	0.002*
MCS	50.5 (10.2)	50.0 (10.8)	50.7 (10.0)	0.566
Mental health	73.8 (19.6)	71.6 (21.1)	74.9 (18.7)	0.208
Social functioning	81.0 (23.0)	76.4 (25.8)	83.3 (21.1)	0.19
Vitality	66.5 (20.5)	61.8 (22.4)	69.0 (19.1)	0.003*
Emotional role limitations	77.3 (26.3)	74.5 (26.5)	78.9 (26.1)	0.118

[a]Statistical significance was determined using Student's *t*-test and the Mann-Whitney U test. *Statistically significant P-values (P values < 0.05). MCS: Mental Component Summary; PCS: Physical Component Summary; SF-36: 36-Item Short Form Health Survey.

Table 5. Multiple Linear Regression Models for the Composite Quality of Life Scores of the SF-36

	Method	Adjusted R^2	F	β (95% CI)	P-value
Model I	OLS	0.24	19.68		
Dependent variable					
PCS					
Independent variables					
Sex (male)				3.6 (1.9, 5.2)	< 0.001*
Age				-0.1 (-0.2, -0.06)	< 0.001*
Educational level				0.6 (-0.02, 1.2)	0.059
Degree of hypertension				-0.6 (-1.2, 0.1)	0.072
Number of comorbidities				-1.3 (-2.1, -0.4)	0.004*
Diabetic peripheral neuropathy				-5.5 (-7.3, -3.8)	< 0.001*
Model II[a]	OLS	0.1	5.42		
Dependent variable					
MCS					
Independent variables					
Sex (male)				4.1 (1.9, 6.3)	< 0.001*
Age				0.2 (0.1, 0.3)	< 0.001*
Married				0.3 (-2.7, 3.2)	0.852
Divorced				2.7 (-2.2, 7.7)	0.278
Common-law union				1.3 (-2.4, 4.9)	0.493
Widowed				-6.7 (-10.9, -2.5)	0.002*
Educational level				-0.3 (-1.1, 0.4)	0.407
Number of comorbidities				0.2 (-0.9, 1.3)	0.755
Diabetic peripheral neuropathy				-1.6 (-3.8, 0.6)	0.161

[a]Being single was used as the reference category for marital status. *Statistically significant P-values (P values < 0.05). CI: confidence interval; MCS: Mental Component Summary; OLS: ordinary least squares; PCS: Physical Component Summary; SF-36: 36-Item Short Form Health Survey.

Regarding MCS scores, the factors associated with a higher score were age (β: 0.18, 95% CI: 0.08 - 0.27) and male sex (β: 4.12, 95% CI: 1.92 - 6.32). In contrast, the only factor associated with a lower MCS score was being widowed (β: -6.71, 95% CI: -10.89 to -2.537) compared to being single.

Discussion

The prevalence of DPN varies greatly depending on the studied population. In the present study, its prevalence was of 33.5%, which could be considered as a high prevalence as it is near the upper limit reported in the scientific literature [22]. Similar to previous studies, DPN was more prevalent in older participants and in those that reported having microvascular complications like CKD [23, 24]. The high prevalence of DPN is clinically important, as there is evidence that this condition is an independent risk factor in patients with diabetes for the development of CVA and can also lead to diabetic foot ulcers and lower limb amputations [25, 26].

It is worrisome that despite its high prevalence, participants reported a low frequency of foot examinations (less than 1 per year) and almost none of them knew they had the condition. This is suggestive of a lack of focus on prevention in the healthcare services received by patients with diabetes. These findings are in accordance with a recent study carried out in five diabetic foot clinics in the Dominican Republic where the majority of patients had advanced stages of diabetic foot and only a few of them assisted for preventive services [27]. It is important to mention that international guidelines recommend that patients with diabetes undergo at least one foot evaluation per year [28].

In contrast with previous research, no association was found between the presence of DPN and vitamin B12 deficiency and dyslipidemia [23, 29]. Our findings were similar to a previous study, where patients with DPN had higher vitamin B12 levels [30]. This finding could be related to the low prevalence of vitamin B12 deficiency which might affect the statistical power to find this association, as this deficiency has lowered as large-scale food fortifications initiatives have been implemented in the Dominican Republic [31].

As expected, participants with DPN had higher levels of HbA1c, fasting blood glucose, and creatinine, which can be interpreted as poor metabolic control [32, 33]. Moreover, the fact that these participants reported a higher use of insulin is

also in agreement with this statement [34].

It is important to point out the fact that the condition most strongly associated with DPN in the regression model was CKD. This association has been reported in multiple previous studies and, since both pathologies share a similar physiopathological mechanism, it is understood that they can both develop simultaneously [24, 35]. On the other hand, diabetic retinopathy, which is also a microvascular complication, did not show a significant association with DPN, in contrast to what has been previously reported [36, 37]. However, diabetic retinopathy was very close to the statistical significance threshold (P = 0.056) and had the second largest effect size in the logistic regression model (OR = 5.1), which suggest that there is a possible association even though P-value significance threshold was not reached. Furthermore, it is possible that many patients with retinopathy still are not aware they have the condition.

The prevalence of vitamin B12 deficiency found in this study (4.5) is consistent with the findings of previous studies, which report a prevalence of this deficiency in Latin America between 2.5% and 35% [38]. Furthermore, participants that used metformin were more frequently deficient as previously reported [17, 39]. However, in contrast with previous findings, an association between vitamin B12 deficiency and age could not be found in the present study [38]. However, it is possible that the low prevalence in the study's sample is limiting the statistical power to find this association.

HRQoL

The presence of DPN significantly affected multiple dimensions of the self-reported HRQoL of participants as previously reported. Previous studies report a global negative effect in QoL for all physical and mental health dimensions of the SF-36 [40, 41]. In contrast, in the present study, the only dimension related to mental health that was affected was the vitality dimension. The lack of self-reported affection of mental health dimensions in the study sample might be due to cultural differences and the stigmatization of mental health problems in the Dominican Republic [42]. Other authors suggest that it is possible that the SF-36 underestimates the impact on mental health of this condition [41].

Male participants reported significantly higher scores in all SF-36 dimensions. This is similar to the findings of several previous studies where male participants had higher scores in multiple QoL dimensions [27, 40, 43]. It is possible that these differences are consequence of intrinsic biological and social differences, or also due to differences in socioeconomic status [44, 45].

Furthermore, participants' age was significantly associated with PCS and MCS dimensions as has also been previously reported [46, 47]. However, in contrast with previous studies, in the present study, age was associated with higher score in the MCS dimension. It is possible that this is a consequence of the recent rise of the burden of mental health conditions in young Dominican adults [48].

Being widowed was another social factor associated with lower scores in the MCS dimension (compared to being single). Comparably, other authors previously reported lower mental health scores in divorced and widowed participants. These authors hypothesize that this could be due to a lack of emotional support and social isolation [40].

Lastly, there was an inverse correlation between the total number of comorbidities and the PCS score. Similar findings have been reported multiple times, where the more comorbidities a participant had the lower their QoL scores in physical and even in emotional/mental dimensions [49, 50]. Interestingly, in the present study, the number of comorbidities did not affect the MCS dimension, which is similar to the findings of recent study carried out with patients with diabetes and polyneuropathy [51].

Limitations

The main limitation of the present study is that it was only carried out within two regions of the country with the use of convenience sample. This makes it difficult to extrapolate its findings to other regions of the country. Another important limitation was the lack of complete metabolic parameters in medical records of the participants, which limits the statistical power of the inferences that can be drawn from these variables and their integration to regression models. Lastly, there was slow recruitment speed due to the large amount of exclusion criteria which impeded reaching the target sample size of 385 participants.

Despite these limitations, the present study has several strengths. The sample size of 367 participants is still significant, allowing to estimate DPN prevalence with a 5% margin of error, considering that the real population prevalence of DPN is most likely less than 50%. To the authors' knowledge, this is the first research study that objectively calculates the prevalence of DPN and evaluates its impact on HRQoL and association with vitamin B12 levels in the Dominican population.

Conclusions

There is a high prevalence of DPN and low patient awareness of the condition. The factors most strongly associated with the presence of DPN were past medical history of CKD, CVA, and age, while vitamin B12 deficiency was uncommon and no association was found with the presence of DPN. The presence of DPN had a negative impact in all QoL dimensions related to physical health and the vitality dimension, meanwhile vitamin B12 showed no effects on QoL. These findings underscore the need for awareness and prevention interventions for both patients and healthcare professionals, as well as more research that evaluate the impact of vitamin B12 deficiency on DPN and HRQoL.

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Conflict of Interest

The authors declare that they have no competing financial or competing interests with the execution or publication of this research study.

Informed Consent

All participants gave their informed consent prior to their participation in the study.

Author Contributions

Berniza Calderon: conceptualization, methodology, funding acquisition, supervision, and writing - review and editing. Manuel Soto: conceptualization, methodology, project administration, formal analysis, validation, visualization, writing - original draft, and writing - review and editing. Nadja Garcia: investigation, project administration, and writing - original draft. Sahel Ghazanfari: investigation, data curation, and writing - original draft. Janet Velez: investigation, validation, and writing - review and editing. Sherezade Hasbun: funding acquisition, investigation, and writing - review and editing.

Data Availability

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author.

Abbreviations

ADA: American Diabetes Association; BMI: body mass index; CI: confidence interval; CKD: chronic kidney disease; CONABIOS: Consejo Nacional de Bioetica en Salud; CVA: cerebrovascular accident; DM: diabetes mellitus; DPN: diabetic peripheral neuropathy; HbA1c: hemoglobin A1c; HDL: high-density lipoprotein; HRQoL: health-related quality of life; INTEC: Instituto Tecnologico de Santo Domingo; LDL: low-density lipoprotein; MCS: Mental Component Summary; OLS: ordinary least squares; OR: odds ratio; PCS: Physical Component Summary; QEIA: quantitative enzyme immunoassay; QoL: quality of life; SD: standard deviation; SF-36: 36-Item Short Form Health Survey; SODENN: Sociedad Dominicana de Endocrinologia y Nutricion; TCSS: Toronto Clinical Scoring System; T2DM: type 2 diabetes mellitus; TSH: thyroid-stimulating hormone; UNIBE: Universidad Iberoamericana

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