

## Original Research Article

# Prevalence and associated factors of peripheral neuropathy in type 2 diabetic patients in Antananarivo: a three-year cross-sectional study

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### ABSTRACT

**Background:** Diabetic peripheral neuropathy (DPN) is common, causing functional disability and impaired quality of life for patients. The aims of this study were to determine the prevalence of DPN and its associated factors in type 2 diabetics seen at the Soavinandriana Hospital Center.

**Methods:** This was a descriptive and analytical cross-sectional study, conducted on a 3-years period. The diagnosis of DPN was made based on a DN4 questionnaire score  $\geq 4$  and/or impaired sensitivity to 10 monofilament and/or a reduction or absence of the Achilles reflex.

**Results:** Among the 289 DT2 patients, the prevalence of DPN was 28.7%. Risk factors for DPN were age 60-69 years [OR=1.83 (1.06-3.19),  $p=0.0139$ ], dyslipidemia [OR=3.31 (1.47-3.49),  $p=0.0009$ ], microalbuminuria [OR=6.98 (3.85-12.9),  $p<0.0001$ ], diabetes duration  $\geq 10$  years [OR=2.80 (1.42-5.52),  $p=0.0011$ ], glycosylated hemoglobin level  $\geq 7\%$  [OR=2.25 (1.03-5.85),  $p=0.0287$ ], presence of nephropathy [OR=13.2 (6.82-26.2),  $p<0.0001$ ], retinopathy [OR=2.71 (1.42-5.15),  $p=0.0009$ ], carotid atherosclerosis [OR=2.73 (1.57-4.79),  $p=0.0001$ ], lower limb arteriopathy [OR=2.27 (1.21-4.23),  $p=0.0047$ ] and ischemic heart disease [OR=3.41 (1.72-6.82),  $p=0.0001$ ].

**Conclusions:** The frequency of DPN was 28.7%. Associated factors were advanced age, the presence of other cardiovascular risk factors, a long duration of diabetes and its poor control, and the presence of other degenerative diabetes complications. Better control of diabetes and associated cardiovascular risk factors with multidisciplinary care are essentials to avoid or limit their occurrence.

**Keywords:** Degenerative complications, Diabetic peripheral neuropathies, Risk factors, Type 2 diabetes

### INTRODUCTION

Diabetes mellitus is one of the most widespread chronic non-communicable diseases in the world. According to the International Diabetes Federation (IDF), in 2024, 588.7 million people worldwide suffered from it, and this number is expected to reach 852.5 million by 2050.<sup>1</sup>

It refers to “a group of metabolic diseases characterized by hyperglycemia resulting from defects in the secretion or action of insulin, or both combined” causing damage to many body’s organs, leading to disabling and life-

threatening health complications such as cardiovascular diseases (CVD), nerve damage (neuropathy), kidney damage (nephropathy), lower-limb amputation, and eye disease (retinopathy).<sup>1</sup>

Among its nervous complications are diabetic peripheral neuropathies (DPN). DPN are defined by a peripheral nerve dysfunction in a diabetic patient after other etiologies have been excluded. Distal symmetric polyneuropathy (DSP) is their most common clinical presentation.<sup>2</sup>

Their pathogenesis is multifactorial, involving complex interactions between glycemic imbalance, the duration of diabetes, age-related neuronal attrition, and other factors such as blood pressure, blood lipid levels, and weight. These abnormalities lead to ischemic events and metabolic disturbances in the nerves.<sup>3,4</sup>

Worldwide, diabetic neuropathy is the most frequent cause of neuropathies, with an estimated prevalence of 6% to 51% in diabetic adults.<sup>3,5</sup> They sometimes lead to debilitating pain, lower limb amputations, and physical disability, consequently reducing quality of life.<sup>6</sup>

Very few studies have been conducted on this subject in Madagascar. One study carried out in 2023 at the endocrinology department of the Joseph Raseta Befelatanana University Hospital found a prevalence of 36% of DPN among type 2 diabetics consulted but this study did not specifically look at the factors associated with the presence of DPN.<sup>7</sup>

The aims of this study were therefore to determine the prevalence of DPN, and to identify the factors associated with its presence in a population of type 2 diabetics in order to improve their management.

## METHODS

This was a descriptive and analytical cross-sectional study exhaustively including all type 2 diabetic patients hospitalized at the Soavinandriana Hospital Center (CENHOSOA) from January 1, 2021 to December 31, 2023 (36 months) in whom a clinical search for diabetic peripheral neuropathy was carried out.

Diabetes was diagnosed based on patient self-reporting or the use of antidiabetic medications. Newly diagnosed diabetes was diagnosed based on the American Diabetes Association (ADA) diagnostic criteria. Type 2 diabetes was suspected if the patient was over 35 years old at the time of diagnosis and/or overweight or obese and/or had a family history of type 2 diabetes, and/or had other cardiovascular risk factors, in the absence of obvious secondary causes of diabetes.<sup>8</sup>

The diagnosis of DPN was purely clinical. It was made in the presence of symmetrical distal sensory symptoms beginning in the lower limbs assessed using the neuropathic pain 4 questionnaire (DN4) with a score  $\geq 4/10$  and/or altered sensation of the foot on examination with a 10 gm monofilament and/or a decrease or absence of the Achilles reflex.<sup>9</sup>

Patients with a pathology or situation likely to give rise to neuropathy were excluded, including chronic alcoholism, spinal cord compression, neurotoxic drugs such as chemotherapy, hypothyroidism and human immunodeficiency virus (HIV) infection as well as those with a neurological or mental disorder that makes the answers to the DN4 questionnaire uninterpretable.<sup>8</sup>

The study population was divided into two groups: those with DPN and those without DPN.

The variables studied were: the presence or absence of DPN; socio-demographic characteristics of the patients including gender and age divided into (30-39 years), (40-49 years), (50-59 years), (60-69 years),  $\geq 70$  years; cardiovascular risk factors associated with diabetes include high blood pressure (HBP), active smoking, overweight or obesity, dyslipidemia, and pathological 24-hour microalbuminuria; and characteristics of diabetes including its duration of evolution, previous antidiabetic treatments [oral antidiabetics (OADs), insulin], the control of diabetes (well controlled if  $HbA1c < 7\%$ , poorly controlled if  $HbA1c \geq 7\%$ ), other chronic degenerative complications of diabetes [retinopathy, nephropathy, ischemic stroke (IS), carotid atherosclerosis (CA), coronary artery disease (CAD), lower limb arteriopathy (LLA) or history of amputation or vascular surgery of the lower limbs].

### *Clinical and paraclinical data*

High blood pressure was confirmed by a blood pressure  $\geq 140/90$  mmHg on at least 2 repeated measurements or a self-declaration of taking antihypertensive medication by the patient.<sup>10</sup>

Dyslipidemia was defined as a low plasma level density lipoprotein cholesterol (LDLc) above the target for the corresponding cardiovascular risk of the patient according to the European Society of Cardiology (ESC) 2019 criteria or taking a lipid-lowering drug.<sup>11</sup>

Microalbuminuria is defined as urinary albumin excretion of between 30 mg and 300 mg in urine collected over 24 hours, or 30 mg/gm or 3 mg/mmol in urine samples.<sup>12</sup>

Patients were considered overweight or obese if their body mass index (BMI) was  $\geq 25$  kg/m<sup>2</sup> or  $\geq 30$  kg/m<sup>2</sup> respectively.

The presence of other degenerative complications of diabetes was determined on the basis of specific anamnestic, clinical and paraclinical criteria for each complication.<sup>8</sup>

The monofilament test was performed using a 10, 5.07-gauge Nylon® monofilament applied perpendicularly to three plantar sites on both feet (opposite the pulp of the first toe and the heads of the first and fifth metatarsals) randomly for one and a half seconds. The application was to be repeated three times on the same site, one of which was a sham application. If two out of three perception errors occurred at a given site, the patient was considered at risk of asymptomatic ulceration due to loss of protective sensitivity.<sup>13</sup>

Data were collected from patient records using a pre-established and pre-tested data collection form. They were

then transcribed into Microsoft Excel and subsequently imported and analyzed using Epi Info™ version 3.5.4®. The statistical analysis consisted of describing and comparing the distribution of patients according to each variable studied in the two groups in order to identify the specific characteristics of patients with DPN.

The statistical tests used for the comparative analysis were the Chi-square test for qualitative variables and the student's test for quantitative variables. The odds ratio (OR) was used as an association measure. It was retained as significant when the value 1 was not included in the 95% confidence interval (95% CI). A p value ≤0.05 was considered statistically significant.

This work was carried out after obtaining the agreement of the director of the establishment, and the head of department. Oral information was provided to each subject participating in the study. The investigations were undertaken only after each participant had signed a free

and informed consent form. The data collected were anonymized before being processed by computer.

## RESULTS

During the study period, 303 patients were included and 14 were excluded. Finally, 289 patients were included in the study, of whom 83 (28.71%) had developed DPN according to the diagnostic criteria for this complication.

The general characteristics of the study population were summarized in Table 1.

The socio-demographic characteristics of patients according to the presence or absence of DPN were reported in Table 2. Gender was not associated with DPN. The mean age of patients with DPN was 65.5±8.2 years versus 61.9±10.4 years for those without DPN, and this difference was statistically significant (p=0.0023). The 60-69 age group was a factor associated with DPN [OR=1.83 (1.06-3.19), p=0.0139].

**Table 1: General characteristics of the study population (n=289).**

Variables	Number (n=289)	Proportion (%)
<b>Gender</b>	Male	149
	Female	140
<b>Age (years)</b>	30-39	10
	40-49	18
	50-59	63
	60-69	136
	≥70	62
<b>Dyslipidemia</b>	227	78.5
<b>HBP</b>	204	70.6
<b>Microalbuminuria</b>	89	30.8
<b>Smoking</b>	76	26.3
<b>Overweight or obesity</b>	35	12.1
<b>Newly diagnosed diabetes</b>	60	20.8
<b>Diabetes duration (years)</b>	1-4	94
	5-9	85
	≥10	50
<b>Antidiabetic OAD</b>	140	48.4
<b>Antidiabetic insulin</b>	67	23.2
<b>No antidiabetic treatment</b>	42	14.5
<b>Antidiabetic OAD + insulin</b>	40	13.9
<b>HbA1c ≥ 7%</b>	241	83.4
<b>HbA1c &lt;7%</b>	48	16.8
<b>Microangiopathies</b>	111	38.4
<b>Nephropathy</b>	73	25.3
<b>Retinopathy</b>	58	20.1
<b>Macroangiopathies</b>	161	55.7
<b>CA</b>	120	41.5
<b>CAD</b>	63	21.8
<b>IS</b>	58	20.1
<b>LLA</b>	48	16.6

CA: carotid atherosclerosis; CAD: Coronary artery disease; HbA1c: glycated hemoglobin; IS: ischemic stroke; LLA: lower limb arteriopathy; OAD: oral antidiabetic drug.

**Table 2: Socio-demographic characteristics associated with the presence of DPN (n=289).**

Variables	DPN		OR (95 % CI)	P value		
	Present (n=83)	Absent (n=206)				
Gender (%)	Female	43 (51.8)	97 (47.1)	1 (Reference)	0.2754	
	Male	40 (48.2)	109 (52.9)	0.82 (0.48-1.42)		
Average age, years (±SD)	65.5 (±8.2)	61.9 (±10.4)		0.0023*		
Age (%)	30-39	0 (0)	10 (4.9)	1 (Reference)	0.0018*	
	40-49	0 (0)	18 (8.7)			
	50-59	17 (20.5)	46 (22.3)	0.89 (0.44-1.73)		0.4308
	60-69	48 (57.8)	88 (42.7)	1.83 (1.06-3.19)		0.0139*
	≥70	18 (21.7)	44 (21.4)	1.02 (0.51-1.95)		0.5334

CI: confidence interval; DPN: diabetic peripheral neuropathy; ND: not defined; OR: odds ratio; \*p value <0.05; SD: standard deviation.

**Table 3: Other cardiovascular risk factors associated with the presence of DPN (n=289).**

Variables	DPN		OR (95% CI)	P value
	Present (n=83)	Absent (n=206)		
Dyslipidemia (%)	75 (90.4)	152 (73.8)	3.31 (1.47-3.49)	0.0009*
HBP (%)	62 (74.7)	142 (68.9)	1.33 (0.73-2.49)	0.2038
Microalbuminuria (%)	51 (61.4)	38 (18.4)	6.98 (3.85-12.9)	<0.0001*
Smoking, (%)	27 (32.5)	49 (23.8)	1.54 (0.84-2.79)	0.0849
Overweight or obesity (%)	13 (15.7)	22 (10.7)	1.55 (0.67-3.43)	0.1642

CI: Confidence interval; DPN: Diabetic peripheral neuropathy; HBP: High blood pressure; OR: Odds Ratio; \*p value <0.05.

**Table 4: Diabetes characteristics associated with the presence of DPN (n=289).**

Variables	DPN		OR (95% CI)	P value
	Present (n=83)	Absent (n=206)		
Average duration, year (±SD)	7.63 (±6.47)	4.46 (±4.79)	---	<0.0001*
Newly diagnosed diabetes (%)	16 (19.3)	44 (21.4)	1 (Reference)	
1-4 years (%)	17 (20.5)	77 (37.4)	0.43 (0.22-0.81)	0.0035*
5-9 years (%)	28 (33.7)	57 (27.7)	1.33 (0.74-2.37)	0.1886
≥10 years (%)	24 (28.9)	26 (12.6)	2.80 (1.42-5.52)	0.0011*
Antidiabetic OAD (%)	44 (53.0)	96 (46.6)	1.29 (0.75-2.22)	0.1958
Insulin (%)	21 (25.3)	46 (22.3)	1.18 (0.61-2.21)	0.3456
No antidiabetic (%)	4 (4.8)	24 (11.7)	0.39 (0.09-1.17)	0.0541
OAD + insulin (%)	8 (9.6)	32 (15.5)	0.58 (0.22-1.36)	0.1289
HbA1c <7% (%)	8 (9.6)	40 (19.4)	1 (Reference)	
HbA1c ≥7% (%)	75 (90.4)	166 (80.6)	2.25 (1.03-5.85)	0.0287*
Microangiopathies (%)	78 (94.0)	33 (16.0)	79.8 (29.7-272)	<0.0001*
Nephropathy (%)	51 (61.4)	22 (10.7)	13.2 (6.82-26.2)	<0.0001*
Retinopathy (%)	27 (32.5)	31 (15.0)	2.71 (1.42-5.15)	0.0009*
Macroangiopathies (%)	66 (79.5)	95 (46.1)	4.51 (2.42-8.79)	<0.0001*
CA (%)	49 (59.0)	71 (34.5)	2.73 (1.57-4.79)	0.0001*
LLA (%)	27 (32.5)	36 (17.5)	2.27 (1.21-4.23)	0.0047*
IS (%)	15 (18.1)	43 (20.9)	0.83 (0.40-1.66)	0.3582
CAD (%)	25 (30.1)	23 (11.2)	3.41 (1.72-6.82)	0.0001*

CA: carotid atherosclerosis; CAD: coronary artery disease; CI: confidence interval; DPN: diabetic peripheral neuropathy; HbA1c: glycated hemoglobin; IS: ischemic stroke; LLA: lower limb arteriopathy; OAD: oral antidiabetic drug; OR: Odds ratio; \*p value <0.05.

Other cardiovascular risk factors associated with the presence of DPN were dyslipidemia [OR=3.31 (1.47-3.49), p=0.0009] and the presence of pathological microalbuminuria [OR=6.98 (3.85-12.9), p<0.0001] as shown in Table 3.

The characteristics of diabetes associated with the presence of DPN were represented in Table 4. In this case, a duration of diabetes ≥10 years as well as poorly controlled diabetes (HbA1c≥7%) were associated with DPN with OR=2.80 (1.42-5.52), p=0.0011 and OR=2.25

(1.03-5.85),  $p=0.028$  respectively. Likewise for the presence of microangiopathic complications [OR=79.8 (29.7-272),  $p<0.0001$ ], namely diabetic nephropathy [OR = 13.2 (6.82-26.2),  $p<0.0001$ ] and diabetic retinopathy (OR=2.71 (1.42-5.15),  $p=0.0009$ ), as well as macroangiopathic complications [OR=4.51 (2.42-8.79),  $p<0.0001$ ], including carotid atherosclerosis [OR=2.73 (1.57-4.79),  $p=0.0001$ ], lower limb arteriopathy [OR=2.27 (1.21-4.23),  $p=0.0047$ ], and coronary artery disease [OR =3.41 (1.72-6.82),  $p=0.0001$ ].

## DISCUSSION

In the present study, the hospital prevalence of DPN was 28.71%. DPN prevalence varies between studies. This prevalence was similar to those reported by Kisozi et al in Uganda (29.4%) and Ponirakis et al in Qatar (23.9%).<sup>14,15</sup> However, it was lower than that reported locally in the endocrinology department of Joseph Raseta University Hospital, Befelatanana by Raheison et al (36%).<sup>7</sup> Agyekum's team in Ghana reported in their study that 20.6% of patients presented with confirmed DPN based on abnormal perception of the vibration test and 35.6% with DPN based on clinical symptoms.<sup>16</sup> Using the Michigan Neuropathy Screening Instrument (MNSI) score to diagnose DPN, Khawaja and his team had found a prevalence of 39.5% in Jordan.<sup>17</sup> Thus, the prevalence of DPN is influenced by the difference in study populations from one region to another and from one country to another, and especially by the diagnostic criteria.

In the present study, patients with DPN were significantly older than those without DPN, and the 60-69-year age group was significantly associated with DPN. Similarly, Ponirakis et al in Qatar, Negussie et al in Ethiopia and Amour et al in Tanzania have all objectively shown that age >60 years was an independent risk factor for DPN.<sup>15,18,19</sup>

Indeed, advanced age increases stress oxidative activity, promotes the stimulation of counter-regulatory signaling pathways and mitochondrial dysfunction. This increases the risk of inflammation and peripheral nerve damage, paving the way for neuroperfusion injury (DPN).<sup>20-22</sup>

In the present study, dyslipidemia and microalbuminuria were identified as risk factors for diabetic neuropathy. Other authors have also reported the same finding for dyslipidemia.<sup>15,17</sup> Indeed, according to the literature, dyslipidemia is implicated in the pathogenesis of diabetic neuropathy through a dual mechanism: direct via neuronal damage caused by the action of oxidized insulin low-density excess lipoprotein (LDL-Ox) during dyslipidemia and indirectly through nerve ischemia secondary to the development of atherosclerosis in the vasa nervorum.<sup>23,24</sup> Microalbuminuria and macroalbuminuria have also been reported as being associated with the presence of DPN by Pai's team in Taiwan.<sup>25</sup> This association supports the theory of a vascular etiology of diabetic peripheral neuropathy, which it shares with diabetic nephropathy, the

first sign of which is the presence of microalbuminuria. Furthermore, microalbuminuria is an important biochemical marker for assessing risk factors for microvascular complications in type 2 diabetes.<sup>26</sup> Contrary to the results of other studies, ours did not find a significant association between HBP and the presence of DPN.<sup>27,28</sup> In any case, optimizing blood pressure control is always recommended to prevent or delay the onset of DPN, given that HBP induces endothelial dysfunction and damages the vasa nervorum, leading to the development of DPN.<sup>29</sup> Similarly, it is associated with chronic low-grade inflammation, which is detrimental to nerve function and the progression of DPN.<sup>30</sup>

The mean duration of diabetes in our patients with DPN was significantly longer than in those without DPN (7.63 years versus 4.46 years), and a duration  $\geq 10$  years was a risk factor for DPN. The same trend was also observed by Jaiswal et al. in their study (8.6 years versus 7.6 years).<sup>31</sup> Jember et al also found that duration of diabetes  $\geq 10$  years was a risk factor for DPN.<sup>32</sup> For Mekuria Negussie et al, duration of diabetes >5 years already promoted the occurrence of DPN.<sup>18</sup> Indeed, a long duration of diabetes corresponds to prolonged exposure to chronic hyperglycemia which activates several metabolic pathways, causing oxidative stress in diabetics neurons and leading to nerve damage and neuronal ischemia.<sup>33,34</sup> Hence the importance of regular screening for PND, particularly in subjects whose diabetes has been progressing for a long time.

Contrary to the results of other authors, we did not find an association between previous antidiabetic drugs used by patients, including insulin, and the existence of DPN.<sup>35</sup> In fact, insulin therapy is more of an indicator of poorly controlled diabetes than a factor of complications. Moreover, while in these other countries, insulin therapy is only initiated when the combination of several oral antidiabetic agents fails, in Madagascar, it is prescribed fairly rapidly because the combination of several antidiabetic drugs is too expensive and insulin therapy seems cheaper. It should be noted that the insulin most widely used in Madagascar is still regular insulin.<sup>7</sup>

Poorly controlled diabetes, as evidenced by an HbA1c level  $\geq 7\%$ , increased the risk of DPN by 2.25 in this study. For Kuate-Tegueu et al in Cameroon, an HbA1c level >7.5% increased this risk by 9.2.<sup>36</sup> Strict long-term glycemic control would therefore be one of the pillars of preventive approaches to DPN.<sup>37</sup>

The association of DPN with other degenerative complications of diabetes (microangiopathies including nephropathy and retinopathy, and macroangiopathies including carotid atherosclerosis, lower limb arteriopathy, and coronary artery disease) has also been observed by other authors. Khawaja et al found a significant relationship between DPN and cardiovascular complications, as well as diabetic retinopathy, in their study.<sup>17</sup> Kuate-Tegueu et al found that the presence of

DPN was associated with chronic kidney disease.<sup>36</sup> In the study by Katulanda et al, the presence of retinopathy predicted the presence of DPN.<sup>38</sup> Indeed, microangiopathy and macroangiopathy share a common pathophysiology, revealing endothelial dysfunction, chronic inflammation, and a prothrombotic state.<sup>39</sup> Thus, the discovery of DPN, the positive diagnosis of which is easily established clinically, should lead to a systematic search for other chronic degenerative complications of diabetes, both microvascular and macrovascular. Their management must be early, appropriate, and multidisciplinary to limit diabetes-related morbidity and mortality.

The study was limited by its retrospective single-center nature, the use of the DN4 score limited to the diagnosis of painful DPN, simple and easy instead of the MNSI score, more complicated but allowing the diagnosis of DPN regardless of its form, as well as the non-performance of nerve biopsy or nerve conduction study.

## CONCLUSION

In conclusion, the frequency of DPN is high among Malagasy patients with type 2 diabetes. It is associated with advanced age, the presence of other cardiovascular risk factors, a long duration of diabetes and poor glycemic control, as well as the presence of other chronic vascular degenerative complications of diabetes.

Screening, prevention, and management must be early, appropriate, and multidisciplinary, particularly in individuals with these risk factors. Investigation for other chronic degenerative complications of diabetes should be systematic upon discovery of DPN, and vice versa. Achieving optimal glycemic control and managing modifiable cardiovascular risk factors are essentials.

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