The Review of DIABETIC STUDIES  RESEARCH ARTICLE

Prevalence of Foot At-Risk and its Associated Characteristics among Outpatients with Diabetes Mellitus in a Peruvian Public Hospital

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Abstract

OBJECTIVE: To assess the prevalence of patients at risk of developing diabetic foot complications (i.e., foot at-risk) and its clinical components according to the updated International Working Group on Diabetic Foot (IWGDF) criteria and to describe demographic and diabetes-related characteristics. METHODS: We conducted a cross-sectional study at María Auxiliadora Hospital between 2017 and 2018. The criteria for foot at-risk in the IWGDF 2019 risk stratification system are classified into four risk categories, R0-R3, ranging from no peripheral arterial disease (PAD) and no peripheral neuropathy (PN) to the presence of PAD or PN in combination with previous foot ulcer, amputation, or end-stage renal disease (R3). According to this system, we obtained prevalence ratios (PR) of foot at-risk categories dependent on sex, age, diabetes duration, and Total Symptom Score. A sample size of 402 subjects was included in the study. RESULTS: Subjects included had a mean age of 61 years, and 66% were female. There were no patients with type 1 diabetes, and 59% percent had a diabetes duration of less than ten years. The prevalence of foot at-risk was 54.3% defined by the IWGDF 2019 criteria, which gave prevalence 17% higher than that defined with the previous 1999 criteria. PN and PAD frequency was 37.3% and 30.1%, respectively. Foot at-risk prevalence was 40% higher in those with severe Total Symptom Score (PR 1.40, 95% CI 1.09-1.80) and also 39% higher in men than in women (PR 1.39, 95% CI 1.17-1.64). Likewise, diabetes duration of more than ten years had a 25% higher prevalence of foot at-risk (PR 1.25, 95% CI 1.05-1.49), and those older than 60 years had a 20% higher presence of this condition (PR 1.20, 95% CI 1.01-1.43). CONCLUSIONS: Our hospital faces a substantial burden of diabetic foot risk in men, patients with long diabetes duration, and those with painful neuropathy. More initiatives are required at primary or hospital level to detect this critical condition. Likewise, reference centers with multidisciplinary teams to apply prevention and therapeutic interventions are urgently needed.

Keywords: diabetes · diabetic foot · risk · IWGDF criteria · primary prevention

1. Introduction

Diabetic foot complications significantly burden public health provision because of the suffering and disability of patients and the direct and indirect costs associated with this condition [1]. The prevalence of diabetic foot ulcers in high-income countries ranges from 8% to 15%, and 85% of amputations are preceded by an ulcer [2]. Despite the magnitude of the problem, few prevention activities are undertaken to reduce the disease burden at primary care health centers [3].

In 1999, the International Working Group of Diabetic Foot (IWGDF) recommended to classify ulceration risk by category, and to educate patients in conducting self-care [4]. This classification categorizes patients at risk of critical diabetic foot complications into four categories, ranging from 0 to 3 (i.e., R0, R1, R2, R3), with each category predicting ulcer occurrence of 5.1%, 14.3%, 18.8%, and 55.8%, respectively, at three years of follow-up [5]. Many countries have implemented detection systems based on this initiative at both primary and hospital level [6-13]. There are other systems that include almost all the clinical components [14-16], which are useful to determine patients at risk of foot problems [17].

In order to predict the occurrence of ulceration accurately, some authors have recommended subdividing IWGDF categories 2 and 3 because they contain heterogeneous factors [18]. However, a recent
systematic review concluded that PAD had the same risk as PN [19], which resulted in the modification of the criteria after they had been established for 20 years to prevent misclassification and its consequent poor follow-up, especially in those under diagnosed [20].

Many prevention programs worldwide use the previous 1999 criteria, but no series has been published to date that employs the new 2019 criteria that followed the recent update. There is a need to evaluate the possible change in the prevalence of diabetes patients at risk of foot ulceration by means of the new IWGDF criteria [21]. Therefore, we aimed to reassess this prevalence and its clinical consequences as well as to describe the demographic and diabetes-related characteristics in outpatients in a diabetic foot unit of a Peruvian hospital.

### 2. Materials and methods

#### 2.1 Study design

A cross-sectional study was conducted at María Auxiliadora Hospital, Lima, Peru, during 2017 and 2018. In this period, approximately 2,500 patients with diabetes mellitus and low income from the southern region of Lima City attended the endocrinology department at this hospital per year. The diabetic foot at-risk program began in 2015; it offered a prophylactic examination of lower limb injuries in diabetic outpatients. At their first endocrinology consultation during the year all patients were scheduled for a foot at-risk screening.

#### 2.2 Population sample

We included subjects who had their first medical consultation during the recruitment period. Patients with active foot ulcers and conditions that made it difficult to assess the foot at-risk category correctly were excluded from the study. These conditions included:

- Hearing loss
- Cognitive impairment
- Linguistic barriers
- Venous insufficiency
- Leg ulcer
- Toe amputation
- Acute infection
- Incomplete data

Based on a sample size of 402 subjects and assuming an expected proportion of foot at-risk patients of 50%, we calculated a confidence level of 95%, precision rate of 5%, and loss rate of 5%. We included all accessible populations in the analysis.

#### 2.3 Clinical evaluation

An expert-validated form was used for the endocrinology staff at María Auxiliadora hospital according to the Delphi method. The form contained data from clinical and epidemiological history and physical examination of foot at-risk components according to 1999 IWGDF guidelines. Two endocrinologists performed clinical evaluations with good interobserver agreement.

### Abbreviations:

| Abbreviation       | Description                              |
|--------------------|------------------------------------------|
| ABI                | ankle brachial index                      |
| CAD                | coronary artery disease                   |
| CI                 | confidence interval                       |
| IWGDF              | international working group on diabetic foot |
| PAD                | peripheral arterial disease               |
| PN                 | peripheral neuropathy                     |
| PR                 | prevalence ratio                          |

The 1999 IWGDF criteria classify patients into four groups:

1. Low risk (R0): no peripheral neuropathy (PN).
2. Moderate risk (R1): only PN.
3. High risk (R2): PAD or deformity +/- PN.
4. Very high risk (R3): ulcer or amputation history.

The 2019 IWGDF criteria also classify patients into four groups, but the definitions of the categories differ from the 1999 criteria:

1. Low risk (R0): no PAD and no PN.
2. Moderate risk (R1): PAD or PN.
3. High risk (R2): PAD or deformity, PN + deformity, PAD + PN.
4. Very high risk (R3): PAD or PN with one of the following: a previous ulcer or amputation, or end-stage chronic kidney disease [22].

The investigators reclassified patients with the same data to obtain updated classification. Both classifications were employed.

We defined PN as an alteration in two or more neurological tests such as monofilament, 128 Hz tuning fork, and Achilles reflex. Monofilament was applied to the first toe and the first, third, and fifth metatarsal head. The 128 Hz tuning fork test was performed at the interphalangeal joint of the hallux. Regarding Achilles reflex, we evaluated whether there was a reflex absence or slow relaxation phase. We defined PAD as a pulse absence or Ankle Brachial Index (ABI) < 0.9 in any of the following arteries (posterior tibial and pedal, left and right). Patients with arterial calcification (ABI ≥ 1.3) in only some of the arteries were not included in the PAD group. We evaluated four deformities: flat foot, pes cavus, claw/hammertoes, and hallux valgus [22]. Type of symptoms, frequency, and intensity of neuropathy were evaluated using the Total Symptom Score [23,24]. The following scores and related symptoms were considered:

- 0: no symptoms
- 1 to 4.99: mild symptoms
- 5 to 9.99: moderate symptoms
- 10 to 14.99: severe symptoms

To assess foot care education, we verified whether previous foot care counseling (from any health professional) had been received or whether patients had acquired knowledge through other means (some knowledge of foot care). Regarding foot care habits, we explored whether patients had proper foot hygiene.
(clean feet during inspection), nail trimming (straight cut), and proper footwear (wide shoes, no internal seams with cushioning sole). We evaluated pre-ulcerative foot lesions as ungual mycosis, xerosis, limb hair, dorsal and plantar heloma, or interdigital mycosis. The test was considered positive if any injury was present in one of the limbs.

Regarding treatment, patients were classified into three groups, as follows:

1. Dietary management only
2. Oral antidiabetic drugs only
3. Insulin (with or without oral antidiabetic drugs)

2.4 Statistical analysis

We described foot at-risk frequencies and their categories according to the 2019 and 1999 IWGDF criteria, respectively, and the clinical findings of PN, PAD, and biomechanical deformity [22]. In bivariate analysis, we described demographic and clinical characteristics according to the 2019 classification. Pearson’s chi-square test was used to evaluate the association of categoric variables. According to the normality evaluation by the Shapiro-Wilk test for numeric variables, we performed one-way ANOVA or the Kruskal-Wallis test.

In multivariate analysis, we considered a generalized linear model with robust variance, logarithm link, and Poisson distribution, and we obtained crude prevalence rates (PR) for foot at-risk and their 95% confidence intervals according to age, sex, diabetes duration, instruction level, diabetes medication, and Total Symptom Score. We also performed an adjusted model with the same variables [25].

We analyzed the database with STATA version 15.1 and considered a significance level of 0.05.

2.5 Ethics

The María Auxiliadora Hospital Institutional Review Board approved our research protocol, and we followed the principles of the Helsinki Declaration. We did not evaluate subjects directly, but only reviewed clinical records. Names and personal ID numbers were hidden in the database.

3. Results

Between January 2017 and December 2018 we evaluated 1060 foot at-risk forms corresponding to 680 patients. We excluded patients with active ulcers (60 subjects) and those with conditions that impeded a complete evaluation (218 subjects). Finally, in the analysis, we included 402 patients and their clinical files from their first consultation (Figure 1).

Our sample had a mean age of 61 years, and 66% of the subjects were women. We found no type 1 diabetes mellitus patients. The subjects had a median diabetes duration of 7 years, and 45% were users of insulin alone or in combination with oral antidiabetic drugs. Almost half of the patients (46.5%) had not received any information on foot care, and 70% presented inappropriate footwear during the consultation. About 75% presented some symptoms in the lower limbs, such as lancinating pain, tingling, burning, or numbness (Table 1).

Regarding foot at-risk assessment, 54.3% had a
Table 1. Clinical and demographic characteristics of patients who attended the foot at-risk program

| Clinical characteristic | n (%) |
|-------------------------|-------|
| **Age (yr)**            |       |
| Mean ± SD (years)       | 61 ± 11 |
| <50                     | 58 (14.4) |
| 50-59                   | 120 (29.9) |
| 60-69                   | 125 (31.1) |
| ≥70                     | 99 (24.6) |
| **Gender**              |       |
| Male                    | 140 (34.8) |
| Female                  | 262 (65.2) |
| **Education level**     |       |
| Illiterate              | 18 (4.5) |
| Elementary              | 148 (36.8) |
| Highschool              | 194 (48.3) |
| College                 | 42 (10.5) |
| **Diabetes duration (yr)** |     |
| Median (IQR)            | 7 (3 to 13) |
| <10 years               | 239 (59.5) |
| 10-10.9 years           | 11 (27.6) |
| >20 years               | 52 (12.9) |
| **Diabetes medication** |       |
| Only diet               | 22 (5.5) |
| Only oral antidiabetic drugs | 196 (48.8) |
| Insulin + ADO           | 184 (45.7) |
| **Foot care education** |       |
| Some knowledge about foot care | 308 (76.6) |
| Previous foot care counseling | 187 (46.5) |
| **Foot care habits**    |       |
| Proper foot hygiene     | 249 (61.9) |
| Proper nail trimming    | 175 (42.3) |
| Proper footwear         | 278 (69.2) |
| **Total Symptom Score** |       |
| Median (IQR)            | 2.33 (1 to 5) |
| Absent                  | 95 (23.6) |
| Mild (1-4.99)           | 204 (50.8) |
| Moderate (5-9.99)       | 95 (23.6) |
| Severe (10-14.99)       | 8 (1.9) |
| **Pre-ulcerative foot lesions** |          |
| Ungual mycosis          | 279 (69.4) |
| Xerosis                 | 240 (59.7) |
| Limb hair absent        | 228 (56.7) |
| Planter heloma          | 208 (51.7) |
| Interdigital mycosis    | 161 (40.1) |
| Dorsal heloma           | 88 (21.9) |
| **Foot at-risk components** |     |
| Peripheral neuropathya  | 150 (37.3) |
| Peripheral arterial diseasename | 121 (30.1) |
| Deformityc              | 220 (54.3) |
| Previous ulcer          | 51 (12.7) |

**Legend:** aDiagnosed if two or more tests were altered, including monofilament (first toe: first, third, and fifth metatarsal heads), 128 Hz tuning fork at the interphalangeal joint of the hallux, and Achilles reflex in the kneeling position. bDiagnosed if the pulse was absent or Ankle Brachial Index (ABI) < 0.9 in any of the following arteries: posterior tibial and pedal, left and right. cDiagnosed by the presence of flat foot, pes cavus, claw/hammer toes, or hallux valgus. Abbreviations: ADO - oral antidiabetic drug, IQR - interquartile range, PAD - peripheral artery disease, SD - standard deviation.

Discussion:

We found that 55% had some type of deformity; the most common were claw/hammer toe (30%), hallux valgus (25%), and flat foot (13%). Regarding the neurosensory tests, 35% showed alterations in the monofilament test, 32% in the 128Hz tuning fork test, and 32% in the Achilles reflex test. In the vascular examination, 21% had an altered pulse, and 35% had an ABI < 0.9 (Table 3).

In the low-risk group, 51% had deformities and 7% previous ulcers, but no PN or PAD. In the very high-risk group, 95% had PN, 60% PAD, and 31% a deformity (Table 4).

In multivariate analysis, foot at-risk prevalence was 40% higher in those with a moderate to severe Total Symptom Score (PR 1.40, 95% CI 1.07-1.82, p=0.01), and it was 39% higher in men than in women (PR 1.39, 95% CI 1.17-1.64, p=0.001). Likewise, patients with a diabetes duration of more than ten years had a 25% higher prevalence of foot at-risk (PR 1.25, 95% CI 1.17-1.64, p=0.001). We did not find any association with age, educational level, or diabetes medication (Table 5).

Factors that influence this wide range include reference population (general or hospital), local prevalence of diabetes, health system, modifications to the original criteria, and variability in the measurement of PN and PAD. For instance, a local general population study found a prevalence of 13% [13], while hospital-based studies found much higher frequencies because biomechanical deformity was defined as a moderate level of foot at-risk with no association with neuropathy, which raised the prevalence to 78% [11]. PN diagnosis by this classification (1999) does not include neuropathic symptoms. However, we found an moderate, high, or very high risk of foot complications according to the new IWGDF 2019 criteria; 17% more than with the 1999 criteria. PN was found in 37.3% and PAD in 30.1% of all patients (Table 2).

Our study revealed that more than half of outpatients (54.3%) were at risk of developing diabetic foot complications according to the new IWGDF 2019 criteria and were associated with severe Total Symptom Score, male sex, and diabetes duration, which corresponds to other cohort studies [17,26].
Table 2. Foot at-risk prevalence in outpatients with diabetes mellitus

| Risk level | 2019 IWGDF criteria | n (%) | 1999 IWGDF criteria | n (%) |
|------------|---------------------|-------|---------------------|-------|
| R0 (low)   | No PN, no PAD       | 184 (45.7) | No PN              | 252 (62.6) |
| R1 (moderate) | PN or PAD         | 65 (16.2)  | PN                 | 36 (9.0)   |
| R2 (high)  | PN and PAD or PN and deformity | 115 (28.6) | PN and PAD or PN and deformity | 78 (19.4) |
| R3 (very high) | PN or PAD and - Previous ulcer or - Previous amputation or - ESCKD | 38 (9.5) | PN and - Previous ulcer or - Previous amputation | 36 (9.0) |

Legend: Diagnosis of PN if two or more tests were altered, including, including monofilament (first toe; first, third, and fifth metatarsal heads), 128 Hz tuning fork at the interphalangeal joint of the hallux, and Achilles reflex in the kneeling position. Diagnosis of PAD if the pulse was absent or Ankle Brachial Index (ABI) < 0.9 in any of the following arteries: posterior tibial and pedial, left and right. Diagnosis of deformity by the presence of flat foot, pes cavus, claw/hammer toes, or hallux valgus. Abbreviations: ESCKD - end-stage chronic kidney disease, IWGDF - International Working Group on the Diabetic Foot, PAD - peripheral artery disease, PN - peripheral neuropathy.

Table 3. Clinical findings from the foot at-risk evaluation (n=402)

| Foot at-risk component | Characteristic | n (%) |
|------------------------|---------------|-------|
| Biomechanical deformity|               |       |
| Type of deformity      |               |       |
| Claw toes              | 121 (30.1)    |       |
| Hallux valgus          | 100 (24.9)    |       |
| Flat foot              | 52 (12.9)     |       |
| Cavius foot            | 24 (6.0)      |       |
| Number of deformities per subject |   |       |
| None                   | 182 (45.3)    |       |
| 1                      | 158 (39.3)    |       |
| 2                      | 48 (11.9)     |       |
| 3                      | 13 (3.2)      |       |
| 4                      | 1 (0.3)       |       |
| Peripheral neuropathy  |               |       |
| Semmens-Weinstein       | Normal: 8 zones | 261 (64.9) |
| monofilament measurement| Decreased: 1-7 zones | 104 (25.9) |
|                        | Absent: 0 zones | 37 (9.2)   |
| Turning fork 128 Hz    | Normal: ≥ 10 s | 233 (57.4) |
|                        | Decreased: <10 s | 122 (31.3) |
|                        | Absent         | 36 (9.2)   |
| Achilles reflex         | Normal         | 267 (68.3) |
|                        | Reinforced     | 100 (25.3) |
|                        | Absent         | 24 (6.2)   |
| Sensory tests showing altered sensation by subject | None | 187 (46.5) |
|                        | 1              | 65 (16.2)  |
|                        | 2              | 73 (18.2)  |
|                        | 3              | 77 (19.2)  |
| Peripheral arterial disease |           |       |
| Decreased or absent pulse | Right pedia | 72 (18.4) |
|                        | Right posterior tibial | 130 (32.3) |
|                        | Left pedia      | 76 (19.2)  |
|                        | Left posterior tibial | 136 (34.5) |
| Number of altered pulses per patient | None | 318 (79.1) |
|                        | 1 or more       | 84 (20.9)  |
| Arteries with ABI ≥1.3 per patients | None | 296 (83.8) |
|                        | One or more     | 57 (16.2)  |
| Arteries with ABI <0.9 per patients (excluding patients with calcification) | None | 191 (64.5) |
|                        | 1              | 56 (18.9)  |
|                        | 2              | 32 (10.8)  |
|                        | 3              | 4 (1.4)    |
|                        | 4              | 13 (4.4)   |
| Type of artery with ABI <0.9 (excluding results with calcification) | Right pedia | 53 (17.0)  |
|                        | Right posterior tibial | 36 (13.0)  |
|                        | Left pedia      | 51 (15.9)  |
|                        | Left posterior tibial | 44 (15.9)  |
| PAD, according to ABI  | Normal (0.9-1.29) | 191 (54.1) |
|                        | Mild (0.70-0.89) | 79 (22.4)  |
|                        | Moderate (0.50-0.69) | 22 (6.2)  |
|                        | Severe: (<0.50) | 4 (1.1)    |
|                        | Calcification (≥1.3) | 57 (16.2)  |

Legend: ABI - ankle-brachial index, PAD - peripheral artery disease.

We found 16% of patients to have ABI ≥ 1.3 in at least one artery. This finding points to the condition of arterial calcification, which is also called Monckeberg atherosclerosis, but it does not necessarily mean decreased blood flow. We could not classify these patients as having PAD because we did not have a second diagnostic method. Therefore, we did not include them in the PAD group, which may have resulted in the prevalence of PAD being underestimated. Exact PAD diagnosis requires additional methods such as brachial toe index, arterial Doppler ultrasonography, or invasive techniques [28]. Aboyans et al. reported that even subclinical PAD (ABI ≥ 1.5) is associated with coronary artery disease (CAD) and should be considered a predictive condition of CAD [29].

Men were affected by foot at-risk more than women, but women attended for consultation more frequently. Previous clinical studies have shown a higher prevalence of ulcer, re-ulceration, hospitalization, major amputation, and death in men than women [19,30]. Diabetes duration is frequently associated with poor glycemic and metabolic outcome [19]. Prolonged glycemic exposition of arteries in joints is associated with increased stiffness and affects the tibiotalar and hallux phalangeal metatarsal joint [31]. Therefore, they require close monitoring.

5. Public Health Implications

Our results reveal a hidden risk of diabetes complications in patients at risk of ulceration. Usually, local hospitals carry out screening programs for diabetes patients at risk of foot ulceration, but there are not enough health facilities that offer adequate preventive or therapeutic interventions [11,32]. A positive achievement at the government level was the development of a diabetic
## Table 4. Association between clinical characteristics and foot at-risk categories (n=402)

| Clinical characteristic | Risk level | n (%) | p-value |
|-------------------------|------------|-------|---------|
| **Age**                 |            |       |         |
| Mean ± SD (years)       | R0 (n=184)| R1 (n=65)| R2 (n=115)| R3 (n=38)|
| <50                     | 33 (18)    | 11 (17)| 11 (10) | 3 (8)   | 0.120 |
| 50-59                   | 59 (32)    | 17 (26)| 27 (23) | 17 (45) |         |
| 60-69                   | 56 (30)    | 21 (32)| 39 (34) | 9 (24)  |         |
| ≥70                     | 36 (20)    | 16 (25)| 38 (33) | 9 (24)  |         |
| **Gender**              |            |       |         |
| Male                    | 49 (27)    | 22 (34)| 48 (42) | 21 (55) | 0.002 |
| Female                  | 135 (73)   | 43 (66)| 67 (58) | 17 (45) |         |
| **Education level**     |            |       |         |
| Illiterate              | 7 (4)      | 3 (5) | 7 (6)  | 1 (3)   | 0.370 |
| Elementary              | 64 (35)    | 20 (31)| 52 (45)| 12 (32) |         |
| High-school             | 89 (49)    | 36 (56)| 49 (42)| 20 (53) |         |
| College                 | 24 (13)    | 6 (9) | 7 (6)  | 5 (12)  |         |
| **Diabetes duration**   |            |       |         |
| Median (IQR)            | R0 (n=184)| R1 (n=65)| R2 (n=115)| R3 (n=38)|
| <10 years               | 125 (68)   | 39 (60)| 61 (53)| 14 (36) | <0.001 |
| 10-10.9 years           | 45 (24)    | 19 (29)| 35 (30)| 12 (32) |         |
| >20 years               | 14 (8)     | 7 (11)| 19 (17)| 12 (32) |         |
| **Diabetes medication** |            |       |         |
| Diet                    | 11 (6)     | 4 (6) | 6 (5)  | 1 (3)   | 0.180 |
| Oral antidiabetic drugs | 99 (54)    | 34 (52)| 44 (38)| 19 (50) |         |
| Insulin                 | 74 (40)    | 27 (42)| 65 (56)| 18 (47) |         |
| **Foot care education** |            |       |         |
| Knowledge about foot care| 144 (78)   | 51 (79)| 86 (75)| 27 (71) | 0.730 |
| Previous foot counseling| 88 (48)    | 26 (40)| 48 (42)| 25 (66) | 0.050 |
| **Foot care habits**    |            |       |         |
| Proper foot hygiene     | 65 (65)    | 37 (57)| 72 (63)| 21 (55) | 0.570 |
| Proper nail trimming    | 80 (44)    | 27 (42)| 46 (40)| 17 (45) | 0.920 |
| Proper footwear         | 51 (28)    | 14 (21)| 41 (36)| 12 (32) | 0.210 |
| **Total symptom score** |            |       |         |
| Median (IQR)            | R0 (n=184)| R1 (n=65)| R2 (n=115)| R3 (n=38)|
| Absent                  | 53 (29)    | 20 (31)| 18 (16)| 4 (11)  | 0.004 |
| Mild (1-4.99)           | 39 (21)    | 6 (9) | 14 (13)| 5 (13)  |         |
| Moderate (5-9.99)       | 27 (15)    | 11 (17)| 21 (18)| 10 (26) |         |
| Severe (10-14.99)       | 65 (35)    | 28 (43)| 62 (54)| 19 (50) |         |
| **Preulcerative lesions**|          |       |         |
| Ungual mycosis          | 126 (69)   | 48 (74)| 78 (68)| 27 (71) | 0.840 |
| Xerosis                 | 110 (60)   | 39 (60)| 70 (61)| 21 (55) | 0.940 |
| Limb hair absent        | 109 (59)   | 37 (57)| 61 (53)| 21 (55) | 0.760 |
| Plantar heloma          | 92 (50)    | 36 (56)| 62 (54)| 18 (47) | 0.780 |
| Interdigital mycosis    | 67 (37)    | 19 (29)| 57 (50)| 18 (48) | 0.020 |
| Dorsal heloma           | 35 (19)    | 9 (14)| 32 (28)| 12 (32) | 0.050 |
| **Foot at-risk components**|         |       |         |
| Peripheral neuropathy⁵  | 0 (0)      | 36 (56)| 78 (68)| 36 (94) | <0.001 |
| Peripheral arterial disease⁶| 0 (0)   | 29 (45)| 80 (70)| 12 (32) | <0.001 |
| Deformity⁷              | 94 (51)    | 0 (0) | 103 (90)| 23 (60) | <0.001 |
| Previous ulcer          | 13 (7)     | 0 (0) | 0 (0)  | 38 (100) | <0.001 |
foot guide for primary care [33].

Although the foot at-risk diagnosis procedure is an easy-to-use, easily accessible, and non-invasive tool, it is not widely used and there is low physicians’ compliance [34]. Even if physicians diagnose PN or PAD, referrals to specialists are not carried out promptly in many cases [35], which may be due to a lack of understanding of ulceration or amputation and the infrequent occurrence of PN and PAD at the primary healthcare level [36]. The diagnosis could also be problematic at the community level because of the high prevalence of diabetes, limited consultation time, lack of evaluator’s training, or lack of necessary equipment for diagnosis [37].

Applying preventive and therapeutic measures to patients promptly according to their diabetic foot risk has been shown to reduce amputations by 48-78%, hospitalizations by 47-49%, and re-ulcerations by 48% in case series from the US and Europe [38]. Such measures are cost-effective and may even be applied in low income areas [39]. Prevention programs must be applied nationwide, and clinical guidelines give a strong recommendation for their application [40].

6. Limitations

The study’s limitation include the lack of laboratory tests, e.g. for HbA1c or lipid profile. Also, we did not evaluate other comorbidities that may contribute to foot at-risk, such as diabetic retinopathy or chronic kidney disease. Furthermore, the sample may not have been representative of the nationwide population as it represented only one of the less affluent areas of south Lima. Therefore, the results cannot be extrapolated to the entire country. Also, the diagnosis of arterial calcification (ABI ≥ 1.3) needed a second reference test to define the degree of ischemia, either transcutaneous oxygen pressure or arterial wave form pulsatility, but their use was not noted in the records available to us.

Finally, although the study did not aim to compare the classifications (1999 or 2019) in terms of better prediction of feet at risk of ulceration, we applied the updated 2019 definition to a population previously evaluated by the 1999 classification and showed how much the prevalence changed.
used a form which was validated by experts, created by endocrinologists, cardiovascular surgeons, and internists, and which used the IWGDF criteria as a reference. Also, PN diagnosis was made according to the Toronto consensus, and we observed a sufficiently large sample to achieve statistically robust results.

7. Conclusions

Our study revealed that there is a substantial burden of diabetic foot risk, in particular in men, elderly, patients with a long duration of diabetes, and those with painful neuropathy. The study also showed that the IWGDF 2019 criteria are helpful in revealing hidden foot at-risk cases. One out of two subjects with type 2 diabetes mellitus at the Maria Auxiliadora Hospital presented with a foot at risk of ulceration according to the updated guideline of the IWGDF 2019.

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