RISK EVALUATION OF FEET ULCERATION IN PEOPLE WITH DIABETES MELLITUS IN PRIMARY CARE

ABSTRACT

Objective: to evaluate the risk of foot ulceration in people with diabetes mellitus treated in primary care. Method: this is a cross-sectional analytical study carried out in Teresina, Piauí, with 308 patients, including those over 18 years old diagnosed with diabetes mellitus and excluding those with active ulceration and/or neuropathy attributed to other conditions. The data were collected using a sociodemographic, clinical, and risk classification form for the foot ulceration, from February to August 2019. The analysis was based on descriptive and inferential statistics. Results: in the study, 56.5% of the participants were over 60 years old, 59.7% did not perform glycemic control, 56.2% did not practice physical activity, 51.3% were overweight and 54.2% had a degree of risk 1 for foot ulceration. Marital status, occupation, and diabetes mellitus for more than 10 years, inadequate glycemic control, arterial hypertension, dyslipidemia, and obesity had a statistically significant association with the risk of ulceration. Those with dry skin, deformities, ankle reflexes, and altered perception of hallux vibration were more likely to have foot ulcers. We found that the clinical examination of the feet and the preserved sensitivity to the monofilament were protective factors. Conclusion: we observed that the sociodemographic and clinical aspects interfere with the probability of ulceration and most of them present a low risk. Also, in the clinical examination of the feet, changes in vibratory sensitivity and ankle reflex increased the likelihood of ulceration, noting that the classification of the risk of ulceration is essential in assisting people with diabetes mellitus.

Keywords: Diabetes Mellitus; Diabetic Foot; Risk Grade; Foot Ulcer; Primary Health Care.
INTRODUCTION

Diabetes mellitus (DM) is the cause of 14.5% of deaths worldwide each year and about 227 million people are expected to develop the disease in 2040. Brazil is the fourth country with the highest incidence of DM, with about 14.3 million people affected. Due to its chronicity, DM can configure irreversible complications that harm the quality of life of people with this disease. Foot ulceration from the diabetic foot is one of the main causes of hospitalization and amputations.

The prevalence of foot ulceration in people with DM is 4 to 10%; the annual population-based incidence is 1 to 4.1%, and the incidence throughout life can reach 25%. A study in Pernambuco found that the prevalence of diabetic foot was 9% and that 25.6% of lower limb amputations were due to this condition.

Diabetic foot is a syndrome characterized by ulceration, infection, and/or destruction of deep tissues, usually associated with neurological disorders and peripheral vascular disease. As a result of ineffective treatment, there are damages in the lower limbs of people with DM. The periodic examination of the feet for the screening and treatment of disorders is needed, allowing the prevention of possible problems.

The risk evaluation of ulceration investigates the factors that lead to the development of the diabetic foot, through clinical and laboratory tests. Through this strategy, when the nurses assist people with DM, they develop the care plan, recommendations, and necessary referrals, necessary in the Nursing consultation to ensure comprehensive care.

The clinical examination should identify the risk factors predisposing to ulceration, evaluating the plantar protective sensitivity and checking indicative signs of pre-ulceration, as well as dermato-functional disorders, which contribute to the emergence of deformities and foot injuries, preventing the development of complications of DM.

As the exclusive responsibility of the nurse, the Nursing consultation must accurately identify people with DM who are at risk of ulcerations. Thus, the detailed evaluation of the feet is characterized as a primary step in screening the risk of complications in the feet. During the consultation, the nurse must identify the dermatological, musculoskeletal, vascular and neurological changes through rigorous inspection and palpation.

This research is relevant since the situational diagnosis can guide the practice of nurses in primary care to implement the stratification of the risk of foot ulceration, comprehensive care, and self-care guidelines in the routine of care for people with DM, contributing to the prevention of foot ulceration.

Therefore, this study aims to assess the risk of foot ulceration in people with diabetes mellitus who were assisted in primary care.

METHOD

This is an analytical cross-sectional study carried out in Teresina, Piauí, in five basic health units (UBSs) in the health center “Centro-Norte” from February to August 2019 by having a greater number of people with DM.

The sample had 2,000 patients with DM registered in the Hiperdia Program and who performed routine consultations at the health units. Patients older than 18 years old diagnosed with DM were included and those with active ulceration and/or neuropathy...
attributed to other conditions were excluded, for example, paraplegia, tetraplegia, or leprosy.

To calculate the sample, we used the formula for estimating the population proportion for finite populations. The confidence level adopted was 95% (\(\alpha = 1.96\)), the assumed prevalence of 40% (\(p = 0.4\)), the complementary prevalence of 60% (\(q = 0.6\)) and the maximum error of 5% (\(e = 0.05\)), totaling the sample of 308 participants. Sample selection was non-probabilistic for convenience and there was no sample loss.

The data collection was in two stages. In the first stage, the form was filled out with patients using the adapted form for clinical evaluation of lower limbs for the prevention of diabetic foot prepared by Mello, Pires, and Kede, to survey the sociodemographic and clinical aspects of people with DM.

In the second stage, a clinical examination (history, the examination of the feet and reflex tests of the ankle, tuning fork, and monofilament) was carried out to track the predictive factors of foot ulceration, using a form prepared by the authors. In this stage, the classification of the level of risk for ulceration was carried out based on the classification of The International Working Groupon the Diabetic Foot. Grade 0 means the absence of loss of protective sensitivity (PSP) or peripheral arterial disease (PAD) (very low risk); Grade 1 in PSP or DAP (low risk); Grade 2 in PSP and DAP or PSP and deformities in the feet or DAP and deformity in the feet (moderate risk); and Grade 3 in PSP or DAP with a history of ulcer or amputation in the feet (high risk).

The patients who met the inclusion criteria were approached individually and invited to participate in the research. The data were collected in a reserved place and the two stages were at the same time. The independent variables were sociodemographic, clinical and those related to the clinical examination of the feet. The dependent variable was the risk of ulceration.

When approaching the patients, we had guidance about the procedure and the sensations they could manifest. Then, the participants were positioned on a chair or stretcher and the use of each instrument was demonstrated. Then, they were asked to close their eyes so that there was no interference in the responses. The 10 g monofilament was touched in the first, third, and fifth metatarsals and the posterior distal phalanx of the hallux. After the application at each point, the participant was asked if he identified any sensation. Three applications were made to ensure the veracity of the answers, one of which was simulated. The perception of the protective sensitivity to the 10 g monofilament would be normal if two responses from the three applications were correct. The exam was considered altered when at least one of the tested points showed no sensitivity.

During the evaluation of the vibratory sensitivity, the distal end of the 128 Hz tuning fork was struck, perpendicularly to the anterior part of the distal phalanx of the hallux. The object was used twice effectively and once simulated. The test was considered normal when the participant showed sensitivity to vibration at least twice out of three attempts.

During the reflex of the calcaneus tendon, the person should have the lower limbs hanging. Dorsiflexion of the foot was performed by the examiner and, shortly thereafter, the calcaneus tendon was struck with the neurological hammer. If plantar flexion occurred, the test was considered normal; and it was considered changed when the person did not outline the movement.

The data were tabulated in Microsoft Excel version 2013 and processed in the Software Statistical Package for Social Science (SPSS) version 22.0. We used the double typing technique with checking and cleaning the database, using Microsoft Excel version 2013. For the data analysis, descriptive and inferential statistics were performed. In descriptive statistics, we calculated absolute frequency and percentage. In inferential statistics, Pearson’s chi-square and Fisher’s exact tests verified the association between categorical variables. The strength of association between categorical variables was identified by the prevalence ratio (PR) with a 95% confidence interval (CI). Values of \(p <0.05\) were considered significant. We adopted clinical importance as a criterion for selecting reference categories.

This study followed the ethical precepts of Resolution 466/2012, and the Ethics and Research Committee (CEP) of the Universidade Federal of Piauí approved it with CAAE 93628818400005214 and Opinion 2,817,426.

**RESULTS**

In the 308 participants, 56.5% were over 60 years old, 72.1% were female, 71.4% declared to be brown. Regarding marital status, 61.4% had a partner. Incomplete elementary education was in 45.1% of the participants. Also, 31.5% were retired and 64.3% received up to one minimum wage.

The evaluation of clinical aspects revealed 94.8% of patients with type 2 DM; 60.1% did not have the disease for more than 10 years; 59.7% did not perform glycemic control; 72.7% were hypertensive; 67.2% had dyslipidemia, 56.2% did not practice physical activity; and 51.3% were overweight, shown in Table 1.

Of the DM patients assisted in primary care, 86% were never submitted to a feet clinical examination, 65.3% had dry skin and 82.8% had no deformities. The test showed 57.8% of patients with normal ankle reflexes, 54.2% with changes in the perception of vibration, and 65.3% with normal sensitivity to monofilament. The risk of ulceration was grade 1 for 54.2% of patients, shown in Table 2.

Patients without a partner were more likely to have foot ulcers (PR: 1.64; CI: 1.01–2.68; \(p = 0.047\)). Their occupation had also a statistically significant association with the risk of foot ulceration (\(p = 0.033\)), as seen in Table 3.

The variables related to clinical aspects showed a statistically significant association with the foot ulceration risk, except for
Table 1 - Clinical aspects of patients with diabetes mellitus assisted in primary care. Teresina, Piauí - Brazil, 2019 (n=308)

| Variables                                | n | %  |
|------------------------------------------|---|----|
| Type of diabetes                         |   |    |
| Diabetes mellitus type 1                 | 16 | 5.2 |
| Diabetes mellitus type 2                 | 292| 94.8|
| Diabetes for more than 10 years          |   |    |
| Yes                                      | 123| 39.9|
| No                                       | 185| 60.1|
| Blood glucose control                    |   |    |
| Yes                                      | 124| 40.3|
| No                                       | 184| 59.7|
| Systemic arterial hypertension           |   |    |
| Yes                                      | 224| 72.7|
| No                                       | 84 | 27.3|
| Dyslipidemia                             |   |    |
| Yes                                      | 207| 67.2|
| No                                       | 101| 32.8|
| Practicing physical activity             |   |    |
| Yes                                      | 135| 43.8|
| No                                       | 173| 56.2|
| Body mass                                |   |    |
| Normal weight                            | 66 | 21.4|
| Overweight                               | 158| 51.3|
| Grade 1 obesity                          | 70 | 22.7|
| Grade 2 obesity                          | 12 | 4.0 |
| Grade 3 obesity                          | 2  | 0.6 |

The type of diabetes (p = 0.784) and the practice of physical activity (p = 0.262). Patients with diabetes for more than 10 years (PR: 2.92; CI: 1.69-5.05; p <0.001), with inadequate glycemic control (PR: 3.16; CI: 1.91-5.23; p <0.001), hypertensive (PR: 1.75; CI: 1.03-2.95; p = 0.036), with dyslipidemia (PR: 2.26; CI: 1.36-3.75; p = 0.002) and obese (PR: 2.50; CI: 1.34-4.66; p = 0.003) were more likely to have foot ulcers, as shown in Table 4.

We found that the clinical examination of the feet (PR: 0.49; CI: 0.25-0.96; p = 0.049) and the plantar protective sensitivity preserved at 10 g monofilament (PR: 0.02; CI: 0.01-0.09; p <0.001) were protective factors against foot ulceration. However, those with dry skin (PR: 3.13; CI: 1.88-5.19; p <0.001), deformities (PR: 6.68; CI: 2.70-21.85; p <0.001), ankle reflex (PR: 10.72; CI: 5.27-21.79; p <0.001) and perception of hallux vibration (PR: 6.23; CI: 3.76-10.33; p <0.001) abnormalities were more likely to ulcerate the feet, as shown in Table 5.

DISCUSSION

Most participants were female, retired, with a partner, and having a low income. A study developed addressing the same theme

Table 2 - Feet clinical examination of patients with diabetes mellitus assisted in primary care and stratification of the risk of ulceration. Teresina, Piauí - Brazil, 2019 (n=308)

| Variables                                | n | %  |
|------------------------------------------|---|----|
| Feet clinical examination                |   |    |
| Yes                                      | 43 | 14.0|
| No                                       | 265| 86.0|
| Skin appearance                          |   |    |
| Dry skin                                 | 201| 65.3|
| Normal skin                              | 107| 34.7|
| Deformities                              |   |    |
| Yes                                      | 53 | 17.2|
| No                                       | 255| 82.8|
| Ankle reflex                             |   |    |
| Altered                                  | 130| 42.2|
| Normal                                   | 178| 57.8|
| Perception of vibration                  |   |    |
| Normal                                   | 141| 45.8|
| Altered                                  | 167| 54.2|
| Sensitivity to monofilament              |   |    |
| Normal                                   | 201| 65.3|
| Altered                                  | 107| 34.7|
| Risk of ulceration                       |   |    |
| Grade 0                                  | 98 | 31.8|
| Grade 1                                  | 167| 54.2|
| Grade 2                                  | 10 | 3.3 |
| Grade 3                                  | 33 | 10.7|

Table 3 - Association of sociodemographic aspects with the risk of foot ulceration in patients with diabetes mellitus. Teresina, Piauí - Brazil, 2019 (n=308)

| Variables                             | Risk of ulceration | PR | CI 95% | p-value |
|---------------------------------------|--------------------|----|--------|---------|
|                                      | Yes | No  |     |        |
| Elderly                               |     |     |     |       |
| Yes*                                 | 123 | 51  | 1.14| 0.70 - 1.85| 0.619^a|
| No                                  | 91  | 43  |    |        |
| Gender                                |     |     |     |       |
| Male                                 |     |     |     |       |
| Yes*                                | 58  | 28  | 0.87| 0.51 - 1.49| 0.680^b|
| No                                  | 156 | 66  |    |        |
| Female*                              |     |     |     |       |
| With a partner                       |     |     |     |       |
| Yes*                                | 138 | 51  | 1.64| 1.01 - 2.68| 0.047^c|
| No                                  | 76  | 43  |    |        |
| Occupation                           |     |     |     |       |
| Unemployed                           |     |     |     |       |
| Yes*                                | 2   | 6   | _   | _       |
| No                                  | 57  | 36  |    |        |
| Employed                             |     |     |     |       |
| Yes*                                | 60  | 30  | 2.63| 1.39 - 4.95| 0.003^d|
| No                                  | 67  | 33  |    |        |
| Housewife                            |     |     |     |       |
| Yes*                                | 72  | 25  | 2.58| 1.58 - 4.16| 0.001^c|
| No                                  | 23  | 12  |    |        |
| Retired                              |     |     |     |       |
| Yes*                                | 72  | 25  | 2.58| 1.58 - 4.16| 0.001^c|
| No                                  | 23  | 12  |    |        |

* Reference category.
^a Pearson’s Chi-square test;
^b Fisher’s exact test.
Table 4 - Association of clinical aspects with the risk of foot ulceration in patients with diabetes mellitus assisted in primary care. Teresina, Piauí - Brazil, 2019 (n=308)

| Variables                              | Risk of ulceration | PR    | CI 95%     | p-value |
|----------------------------------------|--------------------|-------|------------|---------|
|                                        | Yes (n) (%)        | No (n) (%)  |            |         |
| Type of diabetes                       |                    |       |            |         |
| Diabetes mellitus type 1               | 12 (75.0)          | 4 (25.0)  | 1.33 0.42 - 4.25 | 0.784   |
| Diabetes mellitus type 2               | 202 (69.2)         | 90 (30.8) |            |         |
| Diabetes for more than 10 years        |                    |       |            |         |
| Yes*                                   | 101 (82.1)         | 22 (17.9) | 2.92 1.69 - 5.05 | <0.001  |
| No                                     | 113 (61.1)         | 72 (38.9) |            |         |
| Glycemic control                       |                    |       |            |         |
| Yes                                    | 68 (54.8)          | 56 (45.2) | 3.16 1.91 - 5.23 | <0.001  |
| No*                                    | 146 (79.3)         | 38 (20.7) |            |         |
| Systemic arterial hypertension         |                    |       |            |         |
| Yes*                                   | 163 (72.8)         | 61 (27.2) | 1.75 1.03 - 2.95 | 0.036   |
| No                                     | 51 (60.7)          | 33 (39.3) |            |         |
| Dyslipidemia                           |                    |       |            |         |
| Yes*                                   | 156 (75.4)         | 51 (24.6) | 2.26 1.36 - 3.75 | 0.002   |
| No                                     | 58 (57.4)          | 43 (42.6) |            |         |
| Physical activity                      |                    |       |            |         |
| Yes                                    | 89 (65.9)          | 46 (34.1) | 1.34 0.82 - 2.19 | 0.262   |
| No*                                    | 125 (72.3)         | 48 (27.7) |            |         |
| Obesity                                |                    |       |            |         |
| Yes*                                   | 69 (82.1)          | 15 (17.9) | 2.50 1.34 - 4.66 | 0.003   |
| No                                     | 145 (64.7)         | 79 (35.3) |            |         |

* Reference category. Pearson’s Chi-square test.

also showed the prevalence of DM in women. The predominance of females might be because culturally, women are more careful with their health, a fact that is confirmed by the high demand of this public for health services. Also, in the self-care for the prevention of diabetic foot, men had greater deficits compared to women.

Elderly people were predominant, corroborating research carried out in Rio Grande do Sul with diabetic patients that a large part was 60 to 69 years old. Low education prevailed and, according to research developed in Paraná, the fact that the person a low level of education contributes to ignorance of the disease and adherence to therapy difficult.

Most participants had type 2 DM for less than 10 years and did not perform glycemic control, a situation found in a study in which type 2 DM was prevalent in 95% of patients, and 40.6% had a time of diagnosis of the disease from zero to six years. The most-reported comorbidities evidenced in this study were systemic arterial hypertension (SAH) and dyslipidemia, conditions frequently associated with DM, especially in the elderly population. In their lifestyle, most of them were sedentary and overweight was associated with it. People with DM complications have less quality of life, reinforcing the importance of controlling these comorbidities associated with DM and the routine evaluation of the feet to prevent ulceration.

Most of the participants had classification of grade 1 of the risk of foot ulceration, which indicates PSP or PAD and low risk of ulceration. The frequency of clinical evaluation of the feet of these patients must be done by the nurse or primary care physician every six to 12 months. Research conducted in São Paulo found that 66% of diabetic patients had grade 1 for the risk of ulceration, corroborating this study. The risk classification can screen the factors predisposing to ulceration, which enables early interventions, reducing the number of lower-limb amputations.

In the association of marital status and the risk of foot ulceration, we found that participants without a partner are more likely to develop ulceration in the lower limbs. The presence of a partner contributes positively to the treatment of the disease when overcoming difficulties by providing emotional support, essential in the treatment of DM.

The type of occupation interferes with the risk of foot ulceration. This fact is because most of the participants are retired by age. This finding converges with a study that indicated the predominance of retirees and pensioners. Labor activities, depending on the workload, can also cause ulcerations by causing plantar pressure, reinforcing the importance of using customized shoes, toe spacers and seamless socks to relieve plantar pressure.
main changes were in the perception of vibration in the hallux and in the ankle reflex, which is caused by the deterioration of peripheral nerve endings, resulting in more vulnerability of these people to foot trauma. The loss of the sensation of vibration and the ankle reflex is a significant risk factor for the development of foot ulcers, as these clinical manifestations are associated with diabetic neuropathy.22,23

The change in the perception of hallux vibration increased the probability of foot ulceration by 6.23 times, reinforcing the relevance of this test in screening the risk of ulceration. Despite being recommended by the Brazilian Ministry of Health,4 the hallux vibration perception test performed using the 128 Hz tuning fork is little used by Primary Care nurses to perform the feet clinical examination in people with DM in the Teresina city scenario.

Diabetic patients with altered ankle reflexes were 10.72 times more likely to develop foot ulcers. The ankle reflex test can track peripheral nerve involvement and detect chronic neuropathy.4,24 As it is a predictive factor for foot ulceration as in this study, this test should be performed in the care of diabetic people to ensure a complete foot clinical examination.

People with normal sensitivity to the 10 g monofilament test had a protective factor for foot ulcers. The 10 g monofilament is the material most used by nurses for the screening of diabetic feet in Primary Care because it is part of the skin sensitivity evaluation

| Table 5 - Association of the variables of the clinical examination of the feet with the risk of ulceration in patients with diabetes mellitus assisted in primary care. Teresina, Piauí - Brazil, 2019 (n=308) |
|-----------------------------|------------------|-----------------|------------------|------------------|
| Variables                  | Risk of ulceration | PR      | CI 95%     | p-value |
|                            | Yes n (%)         | No n (%)    |               |        |
| Feet clinical examination  | Yes* 24 (55.8)    | 19 (44.2)   | 0.49          | 0.25 - 0.96 | 0.049 |
|                            | No 190 (71.7)     | 75 (28.3)   |               |        |
| Skin appearance            | Dryskin* 157 (78.1) | 44 (21.9) | 3.13          | 1.88 - 5.19 | < 0.001 |
|                            | Normal 57 (53.3)  | 50 (46.7)   |               |        |
| Deformities                | Yes* 49 (92.5)    | 4 (7.5)     | 6.68          | 2.70 - 21.85 | < 0.001 |
|                            | No 165 (64.7)     | 90 (35.3)   |               |        |
| Ankle reflex               | Altered* 120 (92.3) | 10 (77)   | 10.72         | 5.27 - 21.79 | < 0.001 |
|                            | Normal 94 (52.8)  | 84 (47.2)   |               |        |
| Perception of vibration    | Altered* 152 (91.0) | 15 (9.0)  | 6.23          | 3.76 - 10.33 | < 0.001 |
|                            | Normal 62 (44.0)  | 79 (56.0)   |               |        |
| Sensitivity to mono filament| Altered 105 (98.1) | 2 (1.9)   | 0.02          | 0.01 - 0.09 | < 0.001 |
|                            | Normal* 109 (54.2) | 92 (45.8)  |               |        |

* Reference category.
Pearson’s Chi-square test.
kit in the clinical examination of leprosy and they have access to this device. We can emphasize that 10 g monofilament is effective in screening for diabetic neuropathy, one of the main factors related to ulceration, as it evaluates plantar protective sensitivity, in addition to being painless, simple, fast, low cost and easy to apply.\textsuperscript{25}

Thus, by the importance of the clinical examination of the feet, the nurse in Primary Care should organize the routine of evaluating the feet of diabetic patients in their clientele, aiming at detecting neurological, vascular and dermatological alterations early, in addition to checking other aggravating factors that may contribute to the ulcerative process. In this context, health education focused on self-care should be reinforced with every contact with the patient to prevent ulceration in the feet, since most risk factors are modifiable.\textsuperscript{7}

Because it is a cross-sectional study, the impossibility of establishing the cause and effect relationship of the problem stands out as a limitation of the research.

**CONCLUSION**

We observed that most people with DM had a low risk of foot ulceration since grade 1 prevailed in 54.2\% of patients. The classification of the risk of ulceration is a tool that guides the scheduling of the periodicity of the clinical examination of the feet, with a frequency of reassessment from one to 12 months, depending on the degree of risk that is essential for the continuity of the assistance and early intervention for the prevention of foot ulceration.

We identified that having DM for more than 10 years, inadequate glycemic control, SAH, dyslipidemia, and obesity increase the probability of foot ulceration, highlighting the importance of guidelines for adherence to therapy and healthy lifestyle habits.

Even though the feet clinical examination is the main practice for the prevention of foot ulceration in patients with DM, most reported that they have never been submitted to this care, emphasizing that Nursing care needs to improve. We concluded that dry skin, deformities in the feet, and changes in vibratory sensitivity and ankle reflex increase the probability of ulceration in the feet. Therefore, there is a need for comprehensive care through a complete foot clinical examination to these people with DM for the prevention of diabetic ulcers.

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