Risk assessment for foot ulcers among Tunisian subjects with diabetes: a cross sectional outpatient study

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Abstract

Background

Diabetic foot is an underestimated and redoubtable diabetes complication. The aims of our study were to assess diabetic foot ulcer risk factors according to International Working Group on the Diabetic Foot (IWGDF) classification, stratify patients into risk categories and identify factors associated with higher-risk grade

Methods

Cross-sectional setting over a period of 07 months, patients were randomly selected from the diabetic outpatients attending our unit of diabetology. Questionnaire and clinical examination were made by the same physician. Patients free of active foot ulcer were included.

Results

Among 230 patients evaluated, 10 had an active foot ulcer and were excluded. Five patients (2.27%) had a history of foot ulcer and 3(1.36%) had a lower-limb amputation. Sensory neuropathy, as measured by the 5.07(10g) Semmes-Weinstein monofilament testing, was present in 23.63% of patients, whereas 36.82% had a peripheral arterial disease based on clinical findings, and 43.63% had foot deformities. According to the IWGDF classification, Group 0: 72.72%, Group 1: 5.9%, Group 2: 17.73% and Group 3: 3.63%. After univariate analysis, patients in higher–risk groups were significantly more often female, had higher age and BMI, longer diabetes duration, elevated waist circumference, low school level, retinopathy and hyperkeratosis. Multivariate logistic regression analysis identified 3 significant independent factors associated with high-risk groups: retinopathy (OR=2.529, CI95 [1.131-5.655], p=0.024), hyperkeratosis (OR=2.658, CI95 [1.222-5.783], p=0.014) and school level (OR=0.489, CI95 [0.253-9.44], p=0.033)

Conclusions

Risk factors for foot ulceration were rather common in diabetic outpatients. The screening of diabetic patients at risk for foot ulceration should start early, integrated with sustainable patient education

Background

Diabetic foot ulceration is one of the most severe complications of diabetes. Eighty-five percent of non-traumatic amputations in diabetic patients are preceded by foot injury [1]. The main mechanisms causing the lesions are the peripheral sensory neuropathy (PSN), the peripheral artery disease (PAD), which can be associated in varying degrees, in combination with other factors such as microvascular disease, biomechanical abnormalities and limited joint mobility [2].

It is important to identify diabetics at risk of developing foot lesions using a classification easy to apply in daily practice in order to facilitate diabetic foot assessment and to prioritize high-risk patients for

prevention services. Several risk classification schemes have been developed [3–5]. A classification system has been developed by the International Working Group on the Diabetic Foot (IWGDF) in 1999 [3]. Effectiveness of this system to predict diabetic foot complications has been demonstrated [6]. This classification is based on practical and simple clinical data. The presence of PSN, PAD, deformity and history of ulceration and / or amputation are the components of this classification [3]. In addition to these major contributing factors to foot ulcers, several factors have been demonstrated to be associated with higher risk grade [7].

Data on the prevalence of diabetic people at risk for foot ulceration are missing in Tunisia and are rarely reported in diabetic outpatients [8]. Thus, we aimed in this study to assess diabetic foot ulcer risk factors according to the IWGDF classification, stratify patients into risk categories and identify factors associated with higher-risk grade in diabetic outpatients

Methods

1- Study design

We conducted a cross-sectional study to determine the prevalence of risk factors of foot ulceration (PSN, PAD, deformity and history of ulceration and / or amputation) and then classify the patients according to the IWGDF classification system. We performed an univariate then a multivariate analysis to identify significant factors associated with higher foot ulceration risk

2- Study population

Patients were randomly selected from the diabetic patients attending the diabetes-endocrinology outpatient department in Tahar Sfar hospital in Mahdia over a period of 07 months. The same physician made the interrogatory, the clinical examination and collected complementary exams data from all selected patients at the outpatient department two days per week. We did not include in the study patients with diabetes duration less than 02 months, patients with diabetes secondary to endocrine, pancreatic or genetic diseases, and patients with gestational diabetes.

3- Data collection

The study was conducted during the period from april to october 2017. Study participants had a face-to-face interview with the physician to collect data using a standardized questionnaire. The physician collected the following variables: age, educational level, profession, socio-economic status, living conditions (living alone or with the family), type and duration of diabetes, smoking and alcohol habits, past history of hypertension, dyslipidemia, claudication, revascularization, lower limbs ischemia or confirmed arteritis, amputation, retinopathy, and foot ulceration or complicated diabetic foot.

Then, the physician proceeded to a clinical examination including measurement of blood pressure, waist size, recording of the patient weight and height with calculation of body mass index (BMI), thorough feet

examination searching for the presence of foot ulcers, gangrene, infection or other foot lesions, noting the hygiene, hyperkeratosis areas, toe web intertrigo, foot deformities (flat or hollow foot, clawed, straddled or hammer toes, hallux valgus and / or quintus varus and Charcot's foot) and palpation of the pedic and posterior tibial arteries. Patients having active foot lesion were excluded from the study

The PSN was assessed using the 5.07 (10 g) Semmes-Weinstein monofilament according to the technique suggested by IWGDF [3, 9]. The exam is done in a quiet, relaxed atmosphere. The monofilament is first applied to the patient's hands (or on the elbow or forehead) so that he or she knows what he/she should feel. The patient should not see whether the examiner applies the filament neither where she applies it. Three plantar sites were tested on each foot: at the apex of the hallux, and under the 1st and 5th metatarsal head. The physician applies the filament perpendicular to the surface of the skin with a sufficient force to make it bend. The total duration of the test including filament approach, skin contact and shrinkage should last about 2 seconds. The examiner presses the filament onto the skin and asks the patient if he/she feels the pressure applied (Yes / No) and where he/she feels it (Right Foot / Left). She repeats the application three times at the same site by inserting a "dummy test" in which the filament is not applied

In the last step, the physician collected the results of the latest complementary exams: fasting glycaemia, glycated hemoglobin, plasma creatinine and creatinine clearance, ophthalmic examination, and results of explorations of lower extremities arteries if done

4- Diagnostic criteria

PSN was present if at any site of application of the monofilament, at least two of the three responses were false [3, 9]. Screening of PAD was made on the basis of the patient's medical history and clinical examination. PAD was present if there was an intermittent claudication, or a history of vascular reconstruction or of ischemic foot lesion (necrosis, gangrene) or documented PAD as confirmed by Doppler ultrasound examination of lower extremities arteries or by arteriography, or absence of pedic and posterior tibial pulses in the same side. Hyperkeratosis was diagnosed if presence of callus regarding hyperpression zones of the feet. Diabetes was considered well controlled if glycated hemoglobin was less than 7% and/or fasting glycaemia less than 1.4 g, it was considered poorly controlled if HbA1c more than 10% and/or fasting glycaemia more than 2.5 g and averagely controlled between these values. A patient was considered as having a poor psycho-social status if he was living alone and/or was alcoholic and/or had a serious psychiatric disease and/or had a poor body hygiene.

We classified patients according to the IWGDF system where four grades of increasing severity are identified [3]:

1. Group 0: patients who had no PSN (low risk group)
2. Group 1: patients who had isolated PSN
3. Group 2: neuropathic patients who had foot deformity or PAD
4. Group 3: neuropathic patients who had a history of prior foot ulcer or amputation (highest risk group)

5- Statistical analysis

Statistical analysis was performed using SPSS version 21.0. Quantitative variables were presented as mean ± SD, while qualitative variables were presented as percentage. Comparison between risk groups was done using Pearson's Chi^2 test for qualitative data and T student's test for quantitative data, $p < 0.05$ was statistically significant. In order to identify factors associated with a high risk lesion, we performed an univariate and then a multivariate analysis.

We looked for an association between the high risk groups and the following parameters: age, gender, geographic origin (rural or urban), school level, socio-economic level, duration, equilibrium and type of diabetes, presence of diabetic retinopathy, creatinine clearence, psychosocial state, hypertension, hyperlipidemia, toe web intertrigo, hyperkeratosis, BMI and waist circumference. For the univariate analysis, we compared the different parameters between the group 0 (low risk) and the groups 2 and 3 (high and very high lesion risk) according to IWGDF system.

These variables were tested for significance by a multivariate analysis to identify factors associated independently with high risk lesions. The co-variable adjustments were carried out by logistic regression with a significance of 0.2 and then the differences were considered significant if p 0.05 for a 95% confidence interval.

Results

Among the 230 diabetic patients examined, 10 patients were excluded because they presented during the examination an active foot lesion, 220 patients were available and then included in the study.

There were 114 females and 106 males, sex ratio 0.93. The mean age was 55.07 ± 13.54 years. The distribution of the patients according to the school level was 39% illiterate, 38% primary, 19% secondary and 4% university level. The socio-economic status was low in 10.90%, average in 87.72% and high in 1.36%. The habit of smoking was present in 42 patients all male, 39.62% of the male population study. Two patients were alcoholics and were also smokers. A poor psycho-social status was noted in 10.45% of the population's study.

The mean BMI was 30.38 ± 5.47 kg/m2. An overweight (BMI 25 to 30 kg/m2) was observed in 37.27% and obesity BMI > 30 kg/m2) in 47.72% of the study population. An increased waist circumference was seen in 96.33% of women (> 88 cm), 39.61% of men (> 102 cm), and in 65.90% of the total population.

The majority of the patients were type 2 diabetics (198 cases 90%) including 138 (62.27%) insulin-treated, 10% were type 1 diabetics. The mean duration of diabetes was 9.70 ± 6.59 years, it was less than 5 years in 36.57%. The diabetes was considered to be averagely controlled in the majority of cases (55.91%), well and poorly controlled in 15.91% and 28.18% of the cases successively. Hypertension and dyslipidemia were present in successively 38.18% and 34.54% of the patients

Diabetic retinopathy was observed in 39.17% of the 194 patients examined, divided into 50% non-proliferative, 26.31% pre-proliferative and 23.68% proliferative diabetic retinopathy. The average creatinine clearance, calculated by the Cockcroft method, was 100.90 ± 40.19 ml/min.

Fifty-three patients had toe web intertrigo (24.09%), 76 patients (34.54%) had feet hyperkeratosis. A combination of toe web intertrigo and hyperkeratosis was found in 47 patients (21.36%)

Three patients (1.36%) had a history of amputation (one at the small toe and two trans-metatarsal). Five patients (2.27%) had a history of neuropathic plantar ulceration. Foot deformities were observed in 96 patients (43.63%): quintus varus (79.16%), hallux valgus (50%), overlapping toes (34.37%), flat foot (28.12%), claw toes (27.08%), hammer toes (15.62%), hollow foot (2.08%) and Charcot foot (1.04%). The prevalences of PSN and PAD were 23.63% and 36.82% respectively.

Therefore, the distribution of the patients according to the IWFDF classification was:

Group 0: 160 cases (72.73%) including 42 cases (19.09%) with isolated PAD

Group 1: 13 cases (5.90%)

Group 2: 39 cases (17.73%)

Group 3: 8 cases (3.64%)

After univariate analysis, we found that there was a significant association between risk severity and age, gender, BMI, waist circumference, duration of diabetes, retinopathy, hyperkeratosis and school level. Compared to group 0 (low risk group), groups 2 and 3 (high risk group) were significantly older, were more often females, had android obesity, hyperkeratosis, retinopathy, longer diabetes duration and low school level (Table 1)

There was no significant association between risk severity and socio-economic level, type of diabetes, diabetes control, renal function (creatinin clearence), psychosocial state, hypertension, hyperlipidemia and toe web intertrigo.

Multivariate analysis identified 3 significant factors: the presence of retinopathy (OR = 2.529, 95% CI [1.131–5.655], p = 0.024), hyperkeratosis (OR = 2.658, 95% CI [1.222–5.783], p = 0.014) and school level (OR = 0.489, 95% CI [0.253–9.44], p = 0.033)

Discussion

The present survey is the first done in Tunisia aiming to determine the prevalence of risk factors of foot ulcers and thus classify the patients to risk categories. Our study aimed also to identify factors associated with high risk foot ulcer in order to target future preventive measures. The clinical examination was made by the same physician reducing the bias of changing operator. Population study was randomly selected from patients attending the outpatient diabetology department. We found that 21.36% were high risk patients, and foot deformity was the most contributing factor. There was a clear trend

between the increasing severity of the staging and the presence of retinopathy, hyperkeratosis and low school level. The limits of our study were the small size of the population, and some screening methods we used. Diagnosis of PAD was made on the basis of clinical examination and medical history. Non invasive vascular explorations were not available in our department. These tests have some limitations. Measurement of the ankle brachial index is the most widely used method to diagnose and quantify PAD. However, ankle pressures may be falsely elevated due to calcification of the arteries [9]. In these cases, toe pressure can be useful. The transcutaneous partial pressure in oxygen TcPO2 values are reduced in diabetic compared to non diabetic patients, more markedly in cases of neuroischemic foot compared to arterial controls without diabetes [10]. Measurement of TcPO2 is time consuming and expensive. Screening of PAD in the management of diabetic foot on large scale can be based on clinical findings as we done and as described in the international consensus on the diabetic foot [9]. The recent guidelines of the American Diabetes Association ADA confirm this attitude and recommend that patients with symptoms of claudication or decreased or absent pedal pulses should be referred for ankle brachial index and for further vascular assessment [11]. The ADA also recommend annual 10-g monofilament testing to identify feet at risk for ulceration and amputation [11]. It is a good predictive test of the loss of protective sensation that may be combined with the assessment of vibration sensation using a 128-Hz tuning fork [9, 11], assessment of either temperature or pinprick sensation [11], cotton wisp test, or assessment of Achilles tendon reflexes [9].

The presence of PSN was assessed in our study by the 5.07 Semmes Weinstein monofilament test by the same operator. This test not only screens for the presence of dysfunction but also predicts future risk of foot ulceration as demonstrated by some authors [12, 13, 14]. In these studies, the location and number of sites tested and the definition of the PSN were different. The technique suggested by IWGDF, used in our study, has the advantage to be simple, rapid, not expensive and reproducible [15]. The prevalence of PSN in our study was 23.63%, less than the prevalence found by Malgrange et al. using the same methodology (27.1%) [16] and the results of Assaad-Khalil et al. [17] (29.3%) and Shahbazian et al. [18] (35%) using different sites for the monofilament in the first and a supplementary vibration test in the second.

Diabetic peripheral neuropathy plays a central role in the pathogenesis of foot ulcers. It leads to an insensitive and subsequently deformed foot with areas of elevated pressure when walking [19]. Measurement of foot pressure requires specialized materiel and is not recommended in routine management of diabetic foot. Attentive inspection of the patient’s feet is very important to detect hyperkeratosis and deformities [9]. In our study, the prevalence of foot deformities, 43.63%, was markedly high compared with other studies (20%) [16, 18] but similar to that found by Mugambi et al. in an african population (46%) [8]. These differences could be explained by patients’ age, diabetes duration, subjective criteria of diagnosis and also probably by ethnic differences. The presence of hyperkeratosis is highly predictive of future foot ulceration [20]. In our study, the prevalence of hyperkeratosis was 34.54%. This prevalence is rarely reported in the studies and is highly variable, 3% in the study of Shahbazian et al. [18], 45% in the study of Malgrange et al. [16]. Therefore, foot deformities and hyperkeratosis should be screened periodically in diabetic patients.

Several studies classified diabetic patients according to the IWGDF classification, we compared them to our study in Table 2. Group 0 was the less prevalent in the series of Vibha et al. [21] although it was a community based study. Group 3 was the less prevalent in our series, our center is not specialized in managing diabetic foot. Compared to the other studies, Group 1 was less prevalent in our study, PSN could be under-estimated, the 10 g Semmes-Weinstein monofilament test has been used in combination with other tests in the compared series [8, 18, 21]

Although the IWGDF classification system has been shown to predict diabetic foot complications [6], it may undervalue the impact of PAD and history of amputation. Modified versions of the IWGDF classification have been proposed, individualizing the group of isolated PAD as a risk group [16, 22], or separating the groups of ulceration history or amputation history [22]. In 2008, a modified IWGDF classification was recommended by the ADA and the American Association of Clinical Endocrinologists (AACE) [23].

Factors associated with high risk ulcer in our study were age, diabetes duration, male gender, elevated waist circumference, BMI, retinopathy and hyperkeratosis. A high school level was associated with lower risk ulcer. Age, diabetes duration, retinopathy and nephropathy have been found in different studies by univariate analysis [16, 18, 21, 24]. After multivariate analysis, retinopathy, hyperkeratosis and school level were the only factors identified in our study. Hyperkeratosis and retinopathy were also identified by Leymarie et al. [7], with two other factors diabetes duration and socio-economic status. Vibha et al. [21] also identified socio-economic status, age, sedentary activity and diabetes duration. Shahbazian et al. [18] identified glycated hemoglobin and previous patient training about foot care.

Conclusion

This study was the first study about risk assessment and classification of diabetic foot in this region and its findings can be useful in prevention and management of diabetic foot. High risk patients are old male patients, with a long diabetes duration, complicated by retinopathy, having hyperkeratosis and android obesity. Patients having retinopathy or hyperkeratosis have approximately 2.5 folds higher risk to be high risk patients of foot ulcer, and patients with a secondary or university level education have one half lower risk to be in these categories. Our data highlight the value of a public health policy focusing on prevention by planning a regular screening for foot lesions and education of diabetic patients with a more attention to patients with low school level or having hyperkeratosis and retinopathy. Subsequently, we must focus on awareness of the patients. These measures should be applied to chronic disease outpatient structures in first line facilities, which are the first to deal with diabetic patients.

Abbreviations

ADA:The American Diabetes Association, BMI:Body mass index, IWGDF:The International Working Group on the Diabetic Foot, PAD:peripheral artery disease, PSN:Peripheral sensory neuropathy, TcPO2:The transcutaneous partial pressure in oxygen

Declarations

Ethics approval and consent to participate

The project is approved by the Institutional Ethics Committee, Tahar Sfar Hospital, Mahdia, Tunisia

Informed consent was obtained from all individual participants included in the study. The study has been conducted in accordance with the declaration of Helsinki.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available, due to the possibility of identifying patients through the informations registred in the dataset but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

BZ conceived the idea for the research, wrote the framework and drafted the manuscript. SB participated in the design of the study, performed the clinical examination, collected all clinical and paraclinical data and contributed in analysis and interpretation of data. ZEA, FB and WA helped in the interpretation of data and revision of the paper. WK and MHS critically reviewed the manuscript. All authors read and approved the final manuscript.

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