Validation of a new diabetic foot risk score in Quito

Validation de una nueva puntuación de riesgo para el pie diabético en Quito

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Abstract

Objective: To determine the prevalence of diabetic foot and validate a new ulcer risk score. Methods: Using a diagnostic accuracy model design, one-hundred patients were examined to assess the presence of diabetic foot ulcers followed by the application of an ulcer risk score designed by SIGN. Each parameter was given a value to construct a new scale. After an 8-month follow-up period, the presence of new diabetic foot ulcers was recorded to validate the new risk score. Results: The prevalence of diabetic foot was 11%. The incidence of foot ulcers was 2%. For the new risk score, the sensitivity was 50% and specificity was 97%; the positive and negative predictive values were 25% and 99%, respectively; the positive likelihood ratio was 16 and the negative was 0.52, determining a post-test probability of 55% and 4% for a positive and negative result. Conclusions: The new risk score accurately classifies patients into low or high risk group to develop diabetic foot disease and is a simple test to be used in primary health care.

Keywords: diabetic foot, foot ulcer, diabetes complications, diabetic neuropathies, diabetes mellitus type 2.

Introduction

The diabetes is a chronic disease characterized by a sustained hyperglycemia that causes complications at long term, among which the neuropathy and the diabetic foot are included.1

The prevalence of diabetes worldwide is estimated in 2.8% in the year 2002 and it is expected to be of 4.4% for 2030, representing 366 million of patients. The global mortality was of 5.2% in 2000.2 In Ecuador, the number of patients with diabetes, according to the World Health Organization, was of 341,000 in the year 2000, number that will increase up to 921,000 in 2030.3 Moreover, this disease was the first cause of mortality in the general population, according to the National Institute of Statistics and Census, in 2007, causing 5.7% of all deaths.4

The 7% of the patients with diabetes develop ulcers in the lower limbs,5 being this an important morbidity cause,6 as it represents 20% of the hospital admissions in this group.7 The main consequence that the ulcers entail is the amputation. It is estimated that from the total of diabetic patients, 1% will suffer this complication,8 and from them, 58% will require a new amputation in the contra-lateral lower limb in the next 3-5 years.9 It has been estimated that the mortality in the following 2 years after the first amputation reaches 20-25%.10

The main cause of the ulcers development is the diabetic neuropathy, with its three components: motor, sensitive and autonomus. The motor neuropathy leads to an unbalance of the flexor and extensor muscles,11 with the subsequent deformity of the foot, characterized by prominent metatarsian heads and mallet toes. The sensitive component generates a loss of protector sensitivity that leads to the overload of pressures and to the formation of corns. Finally, the dysfunction of the autonomous systems strengthens this process altering the regulation of the skin blood flow12 and reduces the perspiration, resulting in a dry and cold skin with a tendency to develop fissures.
The chronic peripheral blood failure can be observed in 13% of the patients with diabetes and constitutes an important risk factor for the development of ulcers. Other associated factors are the value of the glycosylated hemoglobin (HbA1c), the reduction of the visual acuity and the history of ulcers or amputation. In addition, the traumatism is a main component and its principal origin is the use of inadequate footwear.

In view of these data, taking into account the care of the diabetic patient, it is necessary to dispose of a prediction tool to allow implementing timely preventive measures. With this objective, some years ago the Scottish Intercollegiate Guidelines Network (SIGN) and the Scottish Care Information-Diabetes Collaboration (SCI-DC) developed a risk stratification tool that includes easy-to-observe clinical parameters and which was recommended in the guidelines of the Royal College of Physicians of Edinburgh. Later, it has been validated in two studies: the first one proves its usefulness to predict ulcers and the second one demonstrates is ability to predict the healing of an ulcer according to each risk group.

In this way, the objective of this work is to apply this tool in selected group of patients of the Ecuadorian clinical practice; first in order to know the prevalence of the diabetic foot and then to build and validate a risk score that simplifies the categorization of the patients, allowing its wide use in primary care services within the context of the Ecuadorian public health.

**Methods**

A validation study of diagnosis test has been designed (figure 1). The sample was of 100 subjects, estimated as from a prevalence of diabetic foot of 7% with a 95% confidence level (alpha error of 0.05) and a precision of 0.05. The patients from the Instituto Médico Vida with T2D diagnoses were considered according to the criteria of the American Diabetes Association. The patients were screened from the database of the Institute. The sampling interval was estimated as from the total of the population, after which one each five places was chosen; the first patient was chosen among all the eligible ones. The list used for the sampling was ordered according to the medical history number. Those subjects who could not attend were replaced by the following in order.

The participants underwent anamnesis, physical examination of the feet and revision of the clinical histories. Risk was determined with the collected information based on the parameters depicted in table 1.

For the evaluation with the monofilament of 10 g of Semens-Weinstein, it was applied on each of the determined sites, with the suf cient force to curve the filament, after which the patient could feel at the back of the feet, lateral to the extensor tendon of the first toe, and the posterior tibial pulse behind the internal malleolus of each ankle. In order to assess the deformity, the patient was asked what type of footwear he was using; the inexistence of deformity was considered as they were wearing regular shoes. In order to assess the incapacity, the patient was requested to reach the feet with the hands and was asked if he could see them clearly.

Additionally, other variables were obtained that were useful to define the characteristics of the sample and that might allow the description of factors associated to a higher risk. The studied variables were sex, age, residence and high-school education.
complete years according to the Ecuadorian system). The nutritional condition was assessed with the body mass index (BMI), using the data recorded on the clinical history. The duration of the disease was studied, as well as the insulin treatment and the HbA1c level.1 The disease complications were investigated according to the following criteria: for the diabetic retinopathy, it has been considered as positive the supply of an ophthalmologic examination to indicate proliferative or non-proliferative diabetic retinopathy, or that the patient received laser treatment;1 for the diabetic nephropathy, the criterion was the evidence of microalbuminuria (30-299 µg/mg of creatinine), of macro-albuminuria (>300 µg/mg of creatinine) or a glomerular filtration index <90 mL/min/1.73 m2 of body surface.1 All the patients were classified according to the Wagner classification system and it was considered positive for ulcer as from level 1.16,17

A follow-up phone control after 8 months was performed, in which the patients have been asked if they showed any sort of injury in the feet within the period of time elapsed since they had been examined. Those who replied affirmatively underwent a physical examination. They followed with the same therapeutic protocol without modification during this period.

A description of the studied sample was performed in the statistical analysis, analyzing the proposed variables and its distribution in each risk group. The prevalence with 95% confidence interval was estimated. For the validation phase, the presence of ulcer in the patients during the follow-up was considered as criterion of reference of “gold standard”.16,17 For the preparation of the new risk score, values were assigned to each variable described in table 1 (1 for negative and 2 for positive), obtaining a level between 5 and 10. Several cut points were obtained as from here and it has been determined that the best of them was to be the one with the highest sensitivity value and combined specificity. Then, the positive and negative predictive values were estimated, as well as the maximum verisimilitude index (MVI), and the pre-test and posttest probability. For this last one, the nomogram developed by Fagan was used.19,20 The analysis was performed with the program SPSS version 11.3 and the DAG Stat Diagnostic and Agreement Statistics.21

All the patients were asked if they wanted or not to take part in the study, they were informed about the need of revising their clinical histories, they were asked for their authorization and confidentiality was guaranteed.22 Likewise, an information sheet was submitted to the subjects with the objectives, methodology, benefits, discomforts and risks arisen from the study, the voluntary nature of their participation, the persons with access to the data and the way that the confidentiality will be kept as well as the name of the responsible investigator and the way to get in touch with him. The acceptance proof was recorded by means of the signature.

Results

Table 2 shows the basal characteristics of the study population and the distribution of the variables according to each risk group of the original scale assigned in the initial assessment.

The first result of the study was the prevalence that was estimated in 11% (95% IC: 5-17). The proportion of patients with active ulcer at the moment of the clinical evaluation was of 2%. These cases were excluded from the next study stage. The incidence found during the follow-up period was of 2%. It is worth mentioning that 7% of the sample showed ulcer history, value

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**Table 2. Characteristics of the study population**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total sample (n = 100)</th>
<th>Low risk (n = 57)</th>
<th>Moderate risk (n = 34)</th>
<th>High risk (n = 9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (male)</td>
<td>44/100 (44%)</td>
<td>30/57 (52.6%)</td>
<td>10/34 (29.4%)</td>
<td>4/9 (44.4%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.35 (± 13.12)</td>
<td>59.07 (± 11.41)</td>
<td>66.21 (± 14.60)</td>
<td>68.56 (± 12.49)</td>
</tr>
<tr>
<td>Diabetes duration</td>
<td>9.67 (± 8.25)</td>
<td>7.26 (± 5.73)</td>
<td>12.41 (± 9.50)</td>
<td>14.56 (± 11.86)</td>
</tr>
<tr>
<td>Uses insulin</td>
<td>23/100 (23%)</td>
<td>6/57 (10.5%)</td>
<td>13/34 (38.2%)</td>
<td>4/9 (44.4%)</td>
</tr>
<tr>
<td>HbA1c</td>
<td>7.87 (± 2.11)</td>
<td>7.68 (± 2.08)</td>
<td>8.32 (± 1.97)</td>
<td>7.33 (± 2.60)</td>
</tr>
<tr>
<td>BMI</td>
<td>27.92 (± 5.18)</td>
<td>27.68 (± 5.58)</td>
<td>27.93 (± 4.74)</td>
<td>29.58 (± 4.24)</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>8/100 (8%)</td>
<td>0/57</td>
<td>4/34 (11.8%)</td>
<td>4/9 (44.4%)</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>9/100 (9%)</td>
<td>1/57 (1.8%)</td>
<td>4/34 (11.8%)</td>
<td>4/9 (44.4%)</td>
</tr>
<tr>
<td>High-school education</td>
<td>63/100 (63%)</td>
<td>41/57 (71.9%)</td>
<td>17/34 (50%)</td>
<td>5/9 (55.6%)</td>
</tr>
<tr>
<td>Lives in Quito</td>
<td>73/100 (73%)</td>
<td>47/57 (82.5%)</td>
<td>22/34 (64.7%)</td>
<td>4/9 (44.4%)</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>16/100 (16%)</td>
<td>0/57</td>
<td>11/34 (32.4%)</td>
<td>5/9 (55.6%)</td>
</tr>
<tr>
<td>Absent pulses</td>
<td>8/100 (8%)</td>
<td>0/57</td>
<td>6/34 (17.6%)</td>
<td>7/9 (77.8%)</td>
</tr>
<tr>
<td>Deformity</td>
<td>3/100 (3%)</td>
<td>0/57</td>
<td>2/34 (6.9%)</td>
<td>1/9 (11.1%)</td>
</tr>
<tr>
<td>Previous ulcer</td>
<td>7/100 (7%)</td>
<td>0/57</td>
<td>0/34</td>
<td>7/9 (77.8%)</td>
</tr>
<tr>
<td>Incapacity</td>
<td>21/100 (21%)</td>
<td>1/57 (1.8%)</td>
<td>15/34 (44.1%)</td>
<td>5/9 (55.6%)</td>
</tr>
</tbody>
</table>

The mean is depicted and in category variables, the absolute/total frequency (proportion). BMI: body mass index; HbA1c: glycosylated hemoglobin.
that when adding the cases with active disease and the incidence results in the mentioned prevalence of 11%.

After the assignation of values and the score preparation, the qualification of each patient was obtained within a range of 5 to 10. The distribution of the sample according to the qualification was as follows: 5 = 56; 6 = 28; 7 = 10 and 8 = 4. Once the follow-up was performed and comparing the score value and the development of ulcers, each cut point was analyzed within the stated range. The result determined that the maximum output of the score was to take place when considered positive (i.e., high risk) the patients who reached a value of 8/10 or higher. The estimated indicators for this value and, consequently, for the same score, are detailed in table 3.

**Discussion**

The prevalence found in the study is within the ranged stated in the literature, which ranges between 2 and 15%. The value of the active ulcers agrees with the one of Abbott et al. The annual incidence of ulcers in patients with diabetes of 2% described by Boulton et al matches with this report, value that is also close to the original validation study. These data suggest that the problem that the diabetic foot represents in this group of the Ecuadorian clinical practice patients does not differ from other countries.

In this context, it has to be pointed out that the sample showed HbA1c levels close to 7%, the BMI was placed close to the superior limit of normality and a few patients showed neuropathy (16% versus values from 23 to 50% of other trials). The duration of the disease was lower than 10 years, and there has been a higher proportion of patients who lived in Quito and who had ended the high-school education. Undoubtedly, this aspect of our sample does not represent the Ecuadorian patient in general, but it is an indicator of the population of the capital and of the urban centers of the country.

The distribution of the variables in each risk sub-group of the initial evaluation was according to what has been expected; otherwise said, the risk factors associated to the diabetic foot (the age, duration of the diabetes, the use of insulin, the classification of Wagner, the BMI and the presence of nephropathy and angiopathy) appeared in a higher proportion in those cases classified as high risk. On the contrary, this proportion was lower in patients living in Quito and with high-school education. These data ratify the capacity of the variables that make up the risk score in order to identify the patients who show the risk factors associated to diabetic foot.

Within the validation analysis, the most outstanding findings were the positive and negative MVI, the same ones that transferred to the nomogram and starting from a pre-test probability of 7% (according to the mentioned prevalence), indicated values of positive pre-test probability of 54% and negative of 4%. Thus, a score of 8 or higher represent an increase of almost 8 times in the possibility of developing ulcers, providing us a firm support to start focused preventive measures added to a strict control of the global management of the diabetic patient. In the same way, a score of 7 or lower allows reducing the risk of ulcer to almost the half.

When comparing these findings with the validation study of the original scale, many similarities were found and the characteristics of the sample were very alike, without forgetting the great difference of the size. Analytically, the unique value that differed relevantly was the sensitivity. In order to state a better comparison, the values of the maximum verisimilitude index of this study were estimated, which were not provided by the authors. The results were as follows: positive MVI 8.43 and negative MVI 0.17; when taken to the nomogram in order to determine the post test probability, generated values of 38 and 1% respectively, based on the prevalence of 7%. In other words, the patients qualified as high risk from the score obtained from the assignation of values have a higher probability of developing ulcer. On the other hand, the negative posttest probability is lower with the original scale.

We have to remark the simplicity for applying the new method, the time that its use requires and its low cost. All these characteristics are of great importance in the framework of the primary care in Ecuador, as it concentrates a great volume of patients with scarce resources. The assignation of values to each variable simplifies the management of the scale and the classification in each risk category.

Other risk classification and prediction systems have been published. Laverty et al. validated a system for ulcers, Mayfield et al. for amputations and Rith-Najarian et al. for ulcers and amputations. However, none of them show the simplicity of risk score application of this study. The classification of the International Working Group on the Diabetic Foot is very similar to the risk score of the SIGN, and has been validated, and has a great clinical applicability. In spite of this, it does not define clearly some of the parameters as the neuropathy and the angiopathy.

As limitations of our study, we can mention the follow-up period, but it can be increased in future trials. The turn arisen from the screening of patients as from an order by the clinical history number is minimal, as the used method ensures an adequate representativeness of the study universe.

Finally, in spite of the validation evidence, the individual assessment of each patient will determine the treatment of each.
The social, economic, family conditions and the concomitant morbidities shall announce the therapeutic scheme to be followed, having the medical criterion always as a maxim.

Conclusions
The developed risk score results valid to classify diabetic patients with high or low risk for foot ulcers. The prevalence of the diabetic foot was of 11%. The proportion of patients with active ulcer was of 2%. The incidence found during the follow-up period was of 2%. The use of the risk score can be recommended as an initial tool for the assessment and care of the feet in diabetic patients.

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Declarations of potential conflict of interests
J.F. Cueca Recalda states that there are no conflicts of interest regarding to the content of this article.

References