Software Validation: Sisped (Diabetic Foot System) As A Diagnostic Support

Ligiane Medeiros Diógenes (✉ ligiane.diogenes@ufersa.edu.br)

UFERSA: Universidade Federal Rural do Semi-Arido <https://orcid.org/0000-0002-5263-1862>

Domingos Augusto Malerbi

Albert Einstein Israelite Hospital: Hospital Israelita Albert Einstein

Naira Horta Melo

SBD: Sociedade Brasileira de Diabetes

Roseanne Montargil Rocha

UESC: Universidade Estadual de Santa Cruz

Bianca de Almeida-Pititto

UNIFESP: Universidade Federal de Sao Paulo

Karla Melo

USP FM: Universidade de Sao Paulo Faculdade de Medicina

Carlos Menandro de Lima Firmino

UFERSA: Universidade Federal Rural do Semi-Arido

Fani Eta Korn Malerbi

PUC-SP: Pontificia Universidade Catolica de Sao Paulo

Elenalda Ferreira dos Santos

Universidade Federal de Sergipe

Leila Maciel Andrade

Universidade Federal de Sergipe

Thaísa de Fátima Almeida Rocha

Universidade Federal de Sergipe

Leticia Adrielle dos Santos

Universidade Federal de Sergipe

Karla Freire Rezende

Universidade Federal de Sergipe

Maria Cândida Ribeiro Parizi

UNICAMP HC: Universidade Estadual de Campinas Hospital de Clinicas

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Abstract

Introduction: Diabetic foot is responsible for 40% to 60% of all non-traumatic amputations. Early and intensive ulcer identification and treatment have been shown to reduce the number of amputations by 45 to 90%. Due to the deficit of low-cost computerized programs and aiming at an improvement in the prevention of diabetic foot complications, the Diabetic Foot System-SISPED was created. Therefore, the present work aims to validate the applicability of this SISPED system.

Methods: 117 clinical foot examination records performed by a team of specialists in the detection of the risk foot were evaluated and lauded. Cases were categorized as having or not a risk foot, and the latter, when diagnosed, was classified as described in the literature. These data were then entered into SISPED. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of the reports were calculated.

Results: The mean age of the participants was 55.3 ± 15.5 years, female gender was predominant (71.8%), the meantime of Diabetes Mellitus (DM) diagnosis was 11.9 ± 9.6 years, and the mean glycated hemoglobin was $8.5 \pm 1.9\%$. Patients had type 1 risk foot in 85.5% of cases and only 12% had normal feet. Analysis of the SISPED results indicated a sensitivity of 92.8%, specificity of 99%, positive predictive value (PPV) of 92.8%, negative predictive value (NPV) of 99%, and accuracy of 98.3%.

Conclusion: Comparison of the results of SISPED reports, which should be used by general practitioners, with those of a professional specialized in diabetic foot showed equivalence in diagnostic accuracy. The SISPED was valid to be implemented in the Brazil's National Health System (SUS), in Sergipe, as a diagnostic support tool for health professionals in the assistance to people with diabetes mellitus.

Introduction

Diabetic foot, according to the International Working Group on the Diabetic Foot (IWGDF), is defined as an infection, ulceration, and/or soft tissue destruction associated with neurological alterations and different degrees of peripheral arterial disease (PAD) in the lower limbs. It is one of the most frequent and feared chronic complications of diabetes because of its consequences: ulceration, infection, and amputation [1]. These complications cover a spectrum ranging from "risk foot" to the most severe diabetic foot disease, including foot ulcers, diabetic foot infections, lower limb claudication, gangrene, and Charcot neuroarthropathy. Regardless of the level of foot complication, these patients have a higher risk of mortality than those without foot complications [2].

The incidence of diabetic foot is 2 to 4% per year and is increasing due to the worldwide prevalence of diabetes mellitus and the increased life expectancy of diabetic patients [3]. A meta-analysis type review suggested that the combined prevalence of diabetic foot ulceration is about 6.3% worldwide and another cohort study conducted in the UK showed that the presence of diabetic foot ulceration is associated with a 5% mortality in the first 12 months and 42% in 5 years [4].

In Brazil, the Brazilian Cooperative Study on Ulcer, Severe Peripheral Neuropathy and Amputation (BRAZUPA) evaluated 1055 diabetic patients referred from Primary Health Care to 19 specialized centers and found that 25.3% of patients had prior history of ulcer, 13.7% of amputation, and 5.3% underwent more than one amputation procedure. At the time of evaluation, 18.6% had at least one active foot ulcer, one-third of patients had neuropathic foot (33.7%), and only 8.5% had isolated ischemic disease [1].

A study conducted between 2014 and 2017 estimated the direct medical costs of "diabetic foot" from the perspective of the Brazilian public health system, reaching \$27.7 million for hospitalization and \$333.5 million for outpatient care, resulting in a total economic burden of \$361 million in 2014 [5]. At the same time, about 85% of these procedures, could be avoided with proper screening [6].

Identifying high-risk diabetic patients through early and continuous assessment is the main action to avoid major complications. American Diabetes Association (ADA) guidelines suggest that foot examination in people with diabetes should be performed annually [3], and changes in foot examination allow an adequate risk classification of diabetic foot, the realization of early intervention, and can change bad outcomes [6, 7, 8, 9].

However, in our reality, foot examination is still very much neglected by Brazilian professionals. More than 50% of patients with diabetes have their foot examinations done incompletely [6].

Due to the scarcity of computer systems that support the diabetic foot examination in primary care, SISPED was created. This free access system combines the findings of clinical examination and classifies the risk of ulceration of the examined patients, as proposed by the International Task Force on the Diabetic Foot. The aim of this system is to provide health professionals with minimal training the same accuracy as professionals specialized in the examination of the diabetic foot [10].

Thus, the objective of this study was to evaluate the applicability of the SISPED software, comparing its accuracy concerning the conventional clinical examination performed to verify if it can be validated for its proposed use.

Methods

This is a descriptive, cross-sectional, quantitative research. It was submitted to the Research Ethics Committee of the Federal University of Sergipe (UFS) and approved under CAEE No. 4202.0.000.107-07.

A total of 117 clinical foot examination records of patients aged over 18 years, of both genders, with type 2 diabetes mellitus (T2DM) were evaluated, which were performed in the period from May 2012 to March 2013, by a team of specialists who routinely work on the detection of the diabetic risk foot in the Diabetic Foot Outpatient Clinic of the Aracaju Medical Specialties Center (CEMAR) of the Aracaju City Hall, Sergipe, Brazil. The following clinical parameters were evaluated: type of treatment in use, fasting and postprandial glycemic values, glycated hemoglobin, and presence of risk factors; the diabetes foot examination was performed, with emphasis on the evaluation of the neurological and peripheral vascular

systems. The nylon 10g monofilament was used to investigate the plantar protection threshold, which was evaluated in three specific points in each foot and in both feet. It was considered altered when the patient did not feel the stimulus in at least one of these points twice.

(Summary of items used for the evaluation of the neurological and peripheral vascular system: tactile sensibility, pain sensitivity, vibration sensitivity, pedal pulses, ankle/arm index, loss of plantar sensibility)

These data were inputted in SISPED that uses an artificial intelligence system that combines the evaluated items that are altered, stratifying the foot into 4 risk classes, being them: risk 0, normal foot or pre-ulcer lesion; risk 1, presence of neuropathy (PSP) or peripheral vascular disease (PAD); risk 2, presence of neuropathy and PAD or deformities plus PSP and/or PAD; and risk 3, previous ulcer and/or amputation. From this combination, the system ranks the risk and suggests the appropriate management and follow-up for each class as directed by the IWGDF [6]. Forms that did not contain reports issued by the service team were excluded.

In order to validate the reports given by the system, a contingency table was created comparing these reports with those given by the expert examiner and calculated according to the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy of these reports, according to the contingency table and the formulas exposed below [11]:

SISPED Report			
Examiner's Report	Normal	Risk	Total
Normal	a	b	a+b
Risk	c	d	c+d
Total	a+c	b+d	a+b+c+d

Sensibility = $a/a+c$;

Specificity = $d/b+d$

PPV = $a/a+b$

VPN = $d/c+d$

Accuracy = $(a + d) / (a + b + c + d)$

Results

Data from 117 files were entered into SISPED. None of the forms entered was excluded, and all had data from the foot evaluation and the report given by the team of specialists in diabetes foot of CEMAR. The

mean age was 55.3 + 15.5 years, the female gender was predominant (71.8%), and most patients were from the city of Aracaju (88%).

The mean time of DM diagnosis was 11.9± 9.6 years. About 10% of patients had T1DM and 90% T2DM. The predominant type of treatment was insulin, corresponding to 53% of the charts; oral drugs came next with 31%, and the combined use of insulin and the oral drug was observed in 16% of the patients. The mean glycated hemoglobin was 8.5 ± 1.9%, fasting blood glucose was 164 ± 66.8 mg/dL, and postprandial blood glucose was 221.3 ± 71.8 mg/dL.

The predominant risk factors in the study patients were hypertension responsible for 48.3%, obesity for 32.6%, and coronary artery disease for 7%. Considering the classification of diabetes foot, the patients had feet at risk 1 in 85.5% of cases, 2 in 2.5% and 12% had normal feet.

Table 1
Clinical data from 117 patients with type 2 diabetes who had their feet evaluated

Gender	Age (mean/years) 55.3 ± 15.5	Time of DM (mean/years) 11.9 ± 9.6	Type 2 DM 105 (90%)
Female 84 (71.8%)			
Insulin (only) 69 (53%)	oral drugs (only) 36(31%)	insulin & oral drugs 12 (16%)	glycated hemoglobin 8.5± 1.9%
fasting blood glucose 164±66.8 mg/dL	hypertension 56 (48.3%)	Obesity 38 (32.6%)	coronary artery disease 8 (7%)

When examined by the expert and by SISPED, 51% of patients were classified as risk 0, 40% at risks 1 or 2 and in 9% of patients were classified at risk 3. Additionally, SISPED found 96.5% of patients with pre-ulcer lesions and 43,5% had a suspect of neuropathy. Table 2 shows, in a dichotomized way, the agreement and disagreement of the two tests.

Table 2
Contingency table shows the results of 117 patients who had their feet evaluated by the expert examiner and by SISPED.

		SISPED		TOTAL
		WITHOUT RISK	WITH RISK	
EXPERT	WITHOUT RISK	13	1	14
EXAMINER	WITH RISK	1	102	103
	TOTAL	14	103	117

The analysis of the SISPED results indicated a sensitivity of 92.8%, specificity of 99%, PPV of 92.8%, NPV of 99%, and accuracy of 98.3%. There were two disagreements between the conclusions of the examiners' and SISPED's reports. In the first case, the examiner considered the presence of plantar callus as a risk of ulceration, but SISPED did not. In the second case, SISPED interpreted a sore admission as a high risk of ulceration, disagreeing with the examiner's interpretation.

Discussion

The socioeconomic and cultural impacts of the diabetic foot and diabetic neuropathy on the world economy are substantial, as they relate to up to one-third of resources spent on diabetes care. There is also a difficult-to-measure cost that includes lost productivity, decreased life quality, rehabilitation costs, and personal expenses. Between 36% and 43% of affected patients reported anxiety, depression, and sleep disturbances [12, 13]. Thus, there is little doubt that increasing the number of feet examined is likely to reduce the impact of DM at public coffers and avoid or minimize risk or harm to subjects.

The challenge to save the diabetes foot is a reality of health systems in the world, given that the outcome of treatment and prognosis of injuries is poor [14, 15]. The CONFI study involved 400 participants recruited from podiatry community and multidisciplinary clinics for diabetic foot ulcers and demonstrated that at the end of 1 year, ulcers had healed in only 46% (and subsequently reappeared in 10% of these), while 15% of patients died and 17% required lower limb amputation [16].

From this perspective, foot examination, a primary prevention resource, is considered a cost-reducing measure in T2DM patients [17]. Patients who have their feet routinely evaluated by specialists cost less to the health system, reducing costs by up to 22.5% in the year before the appearance of ulcers and maintaining this reduction until two years after the appearance of the lesion, in addition to having lower amputations rates [8]. The benefit of the diabetes foot examination for high-risk patients is unquestionable, however, it cannot be disregarded that it is still necessary to find a method of DP examination that has good accuracy and that is cost-effective.

It is known that the implementation of specialized diabetes foot teams can reduce, in the long term, amputation rates in diabetes patients by 62 to 82% [18] and can reduce the risk for new ulcerations and amputation by three times in 1 year [19]. It is undoubtedly cheaper and more effective to perform foot examinations. Any effort that aims to facilitate this evaluation becomes a mandatory measure in strategic health planning [17]. The great difficulty in forming such teams motivated the development of a computer system to facilitate the obtaining of the risk foot report.

The SISPED was implemented following the national PSPD program, by the Sergipe State Department of Health 9 years ago. There is still no work evaluating the impact of its implementation in the state. The program is capable of storing patient data in an organized way, generating reports based on objective parameters capable of assessing foot risk with good accuracy. Its use with data insertion will be able to create a database on the evaluation of the diabetes foot, with several possibilities of analysis that will

help establish strategies besides the possibility of correlating the collected data, for better evaluation of the impact of preventive measures, facilitating the planning of resources [20, 21].

The SISPED was able to separate, with good sensitivity (92.8%) and specificity (99%), the patients with and without risk of ulceration and to suggest the most appropriate conduct and follow-up for each case. Of the patients evaluated, 96.5% had any pre-ulcerative lesions and 43,5% had a suspect of having neuropathy and therefore required education about foot care, assessment for the diagnosis of neuropathy, podiatric treatment and a six-monthly (no longer annual) reevaluation of the diabetic foot and should be evaluated and conducted in the Primary Health Care itself.

Knowing that prevention is the first line of defense against diabetic foot ulcers and their consequences, our results suggest that SISPED can be used by multi-professional teams in Primary Health Care (PHC), for its excellent accuracy and user-friendly interface. In Brazil, prevention performed in the context of PHC by the physician or nurse contributes to the reduction of complications by identifying patients at higher risk for foot ulceration, in addition to implementing prophylactic interventions, including the stimulation of self-care [22]. Comprehensive educational programs, which include the encouragement of self-care, regular foot examination, risk classification, and therapeutic education, can reduce the occurrence of foot injuries by up to 50% [6, 23].

Two cases of disagreement between the expert examiner and SISPED occurred in our study. In the first one, the expert used the previous classification of the IWGDF, in which the examiner considered the presence of plantar callus as a risk 1. In the second case, the SISPED classified as risk 3 a patient with a history of hospitalization for a foot wound, while the expert examiner ruled out this risk, as the hospitalization occurred after motor vehicle trauma. In this sense, we perceive the dependence of SISPED for an accurate data entry by the examiner, so that the proper processing is carried out.

Conclusion

SISPED is an excellent accurate tool for this purpose, and at a low cost. In this scenario, SISPED is validated to be implemented in SUS as a diagnostic support tool for people with diabetes mellitus.

Abbreviations

SISPED

Diabetic Foot System

DM

Diabetes Mellitus

SUS

Brazil's National Health System

IWGDF

International Working Group on the Diabetic Foot

PAD

Peripheral Arterial Disease

UFS

Universidade Federal de Sergipe

T1DM

Type 1 Diabetes Mellitus

T2DM

Type 2 diabetes mellitus

CEMAR

Aracaju Medical Specialties Center

PPV

Positive Predictive Value

NPV

Negative Predictive Value

PHC

Primary Health Care

Declarations

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Not applicable

Authors' contributions

LMD, MCRP, DAM, NHM and KFR conceived of the study, participated in its design and coordination and helped to draft the manuscript. BAP, KM, CMLF, FEKM, BAP, FEKM, LAS contributed to the analysis, data review and writing of the manuscript. TFAR, EFS and LMA collected the data. LMD and MCRP had full access to all study data and was responsible for manuscript submission. All authors read and approved the final manuscript.

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Availability of data and material

Data is available upon request.

DECLARATIONS

Ethics approval and consent to participate

This study was submitted to the Research Ethics Committee of the Universidade Federal de Sergipe (UFS) and approved under CAEE No. 4202.0.000.107-07.

Consent for publication

The authors of this manuscript approve this version to be submitted for publication.

Competing interests

The authors declare no conflict of interest.

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