












RESPONSIVENESS OF THE SINBAD SYSTEM IN THE EVALUATION OF FOOT ULCER RELATED TO DIABETES MELLITUS: A MULTICENTRIC STUDY

Luciana da Silva Barros¹ 
Julliany Lopes Dias² 
Danúbia Mendes e Torres³ 
Cynthia Assis de Barros Nunes⁴ 
Eline Lima Borges⁵ 
Ângela Lima Pereira² 
Maurício Gomes da Silva Neto⁶ 
Marlene Andrade Martins⁷ 
Mônica Antar Gamba⁸ 
Suelen Gomes Malaquias⁴ 
Maria Márcia Bachion¹ 

¹Universidade Federal de Goiás, Programa de Pós-Graduação em Enfermagem e Saúde. Goiânia, GO, Brasil.

²Universidade Federal do Tocantins. Palmas, TO, Brasil.

³Unidade de Referência em Saúde Padre Eustáquio. Belo Horizonte, MG, Brasil.

⁴Universidade Federal de Goiás, Faculdade de Enfermagem. Goiânia, GO, Brasil.

⁵Universidade Federal de Minas Gerais, Escola de Enfermagem. Belo Horizonte, MG, Brasil.

⁶Secretaria Municipal de Saúde de Jataí. Jataí, GO, Brasil.

⁷Universidade Federal de Jataí. Jataí, GO, Brasil.

⁸Universidade Federal de São Paulo, Departamento de Enfermagem em Saúde Coletiva. São Paulo, SP, Brasil.

ABSTRACT

Objective: to analyze the responsiveness of the SINBAD Classification System in the evaluation of diabetes mellitus-related foot ulcers.

Method: multicenter clinimetric research carried out between December 2023 and July 2024, in five cities in Brazil: Palmas (TO), Goiânia and Jataí (GO); Belo Horizonte (MG); and São Paulo (SP). Convenience sampling involved individuals aged ≥ 18 years with diabetes-related foot ulcers. Data were collected through interviews and application of the SINBAD Classification System, in the initial assessment (D_0), in 30 (D_{30}) and 60 days (D_{60}). The Shapiro-Wilk, Friedman, Cochran's Q, and Wilcoxon tests were used for analysis ($p < 0.05$).

Results: of the 113 individuals initially evaluated (D_0), 71 (totaling 77 ulcers) completed the assessments in D_{30} and D_{60} . In the evaluation in D_0 , most had neuropathy (90.9%) and no signs of ischemia in the foot (64.9%). Most ulcers were located on the forefoot, with no signs of infection, limited to the subcutaneous tissue, and with an area $\geq 1\text{cm}^2$, whose median showed a significant decrease in all time intervals evaluated. Regarding the items of the SINBAD system, a significant difference was found for "area" ($p = 0.000$) and "depth" ($p = 0.041$) of the ulcers between D_0 - D_{60} . As to the total score, there was a difference between D_0 - D_{60} ($p < 0.001$) and D_{30} - D_{60} ($p = 0.004$), with an effect size of respectively $r = 0.436$ and $r = 0.333$.

Conclusion: there is evidence of responsiveness of the SINBAD Classification System between D_0 - D_{60} and between D_{30} - D_{60} , with a moderate effect size.

DESCRIPTORS: Nursing. Complications of diabetes. Diabetic foot. Healing. Evaluation studies.

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RESPONSIVIDADE DO SISTEMA SINBAD NA AVALIAÇÃO DE ÚLCERA NO PÉ RELACIONADA À DIABETES MELLITUS: ESTUDO MULTICÊNTRICO

RESUMO

Objetivo: analisar a responsividade do Sistema de Classificação SINBAD na avaliação de úlceras no pé relacionadas à diabetes mellitus.

Método: pesquisa clinimétrica, multicêntrica, realizada entre dezembro de 2023 e julho de 2024, em cinco cidades do Brasil: Palmas (TO), Goiânia e Jataí (GO); Belo Horizonte (MG) e São Paulo (SP). A amostragem por conveniência envolveu indivíduos com idade ≥ 18 anos, com úlcera no pé relacionada ao diabetes. Os dados foram coletados mediante entrevista e aplicação do Sistema de Classificação SINBAD, na avaliação inicial (D_0), em 30 (D_{30}) e 60 dias (D_{60}). Para análise foram utilizados os Testes de Shapiro-Wilk, Friedman, Q de Cochran e Wilcoxon ($p < 0,05$).

Resultados: dos 113 indivíduos avaliados inicialmente (D_0), 71 indivíduos (totalizando 77 úlceras) completaram as avaliações em D_{30} e D_{60} . Na avaliação em D_0 , a maior parte apresentava neuropatia (90,9%) e ausência de sinais de isquemia no pé (64,9%). A maioria das úlceras estava localizada no antepé, sem sinais de infecção, limitadas ao tecido subcutâneo e com área $\geq 1\text{cm}^2$, cuja mediana apresentou diminuição significativa em todos os intervalos de tempo avaliados. Quanto aos itens do sistema SINBAD, foi encontrada diferença significativa para “área” ($p = 0,000$) e a “profundidade” ($p = 0,041$) das úlceras entre D_0 - D_{60} . Quanto à pontuação total, houve diferença entre D_0 - D_{60} ($p < 0,001$) e D_{30} - D_{60} ($p = 0,004$), com tamanho de efeito respectivamente de $r=0,436$ e $r = 0,333$.

Conclusão: há evidências de responsividade do Sistema de Classificação SINBAD entre D_0 - D_{60} e entre D_{30} - D_{60} , com tamanho de efeito moderado.

DESCRITORES: Enfermagem. Complicações do diabetes. Pé diabético. Cicatrização. Estudos de avaliação.

CAPACIDAD DE RESPUESTA DEL SISTEMA SINBAD EN LA EVALUACIÓN DE LA ÚLCERA DEL PIE RELACIONADA CON LA DIABETES MELLITUS: ESTUDIO MULTICÉNTRICO

RESUMEN

Objetivo: analizar la capacidad de respuesta del Sistema de Clasificación SINBAD en la evaluación de las úlceras del pie relacionadas con la diabetes mellitus.

Método: investigación clinimétrica multicéntrica realizada entre diciembre de 2023 y julio de 2024, en cinco ciudades de Brasil: Palmas (TO), Goiânia y Jataí (GO); Belo Horizonte (MG) y São Paulo (SP). El muestreo por conveniencia incluyó a personas ≥ 18 años con úlceras en el pie relacionadas con la diabetes. Los datos fueron recolectados mediante entrevistas y aplicación del Sistema de Clasificación SINBAD, en la evaluación inicial (D_0), en 30 (D_{30}) y 60 días (D_{60}). Para el análisis se utilizaron las pruebas de Shapiro-Wilk, Friedman, Q de Cochran y Wilcoxon ($p < 0,05$).

Resultados: de los 113 individuos evaluados inicialmente (D_0), 71 personas (77 úlceras en total) completaron las evaluaciones en D_{30} y D_{60} . En la evaluación en D_0 , la mayoría presentó neuropatía (90,9%) y ningún signo de isquemia en el pie (64,9%). La mayoría de las úlceras se localizaron en el antepié, sin signos de infección, limitadas al tejido subcutáneo y con un área $\geq 1\text{cm}^2$, cuya mediana mostró una disminución significativa en todos los intervalos de tiempo evaluados. Respecto a los ítems del sistema SINBAD, se encontró diferencia significativa para “área” ($p = 0,000$) y “profundidad” ($p = 0,041$) de las úlceras entre D_0 - D_{60} . Con respecto a la puntuación total, hubo una diferencia entre D_0 - D_{60} ($p < 0,001$) y D_{30} - D_{60} ($p = 0,004$), con un tamaño del efecto de respectivamente $r=0,436$ y $r = 0,333$.

Conclusión: hay evidencia de capacidad de respuesta del Sistema de Clasificación SINBAD entre D_0 - D_{60} y entre D_{30} - D_{60} , con un tamaño del efecto moderado.

DESCRIPTORES: Enfermería. Complicaciones de la diabetes. Pie diabético. Cicatrización. Estudios de evaluación.

INTRODUCTION

It is estimated that approximately half a billion people in the world have diabetes mellitus, with approximately 32 million in South America and Central America. Projections indicate an increase in this amount of, respectively, 46% and 50% by 2045¹. One of its main complications is foot ulcers, which can be classified into ischemic, neuropathic, or neuroischemic (mixed), depending on the presence of peripheral neuropathy, peripheral arterial disease, or both².

A foot ulcer related to diabetes mellitus is any rupture of the skin surrounding the foot, affecting at least the epidermis and part of the dermis in people with diabetes². More severe cases can lead to amputations, reducing quality of life and increasing the risk of premature death in individuals with diabetes mellitus³.

The difficulty of doctors and nurses in early recognition of foot ulcers related to diabetes mellitus, the obstacles to access health services, and the underestimation of the severity of the injury contribute to the worsening of ulcers, the emergence of complications, and the risk of amputation³. In the presence of ulceration, accurate assessment of the lesions is essential, including examination of the area and depth of the lesion, for the presence of infection and ischemia⁴.

Systematic recording of ulcer characteristics is crucial for planning treatment strategies, predicting clinical outcomes, and improving communication among healthcare professionals⁵. In this regard, the use of instruments and systems to evaluate the healing process is required⁶.

Classification instruments, such as Meggit-Wagner⁷, the University of Texas⁵, the Wlfl⁸, and SINBAD⁹, are used to evaluate diabetes mellitus-related foot ulcers. None of the currently available rating, evaluation, or scoring systems are considered gold standard¹⁰.

The SINBAD classification system is a tool for evaluating diabetes mellitus-related foot ulcers, covering six assessment items that give rise to the acronym: *Site (S)*, *Ischemia (I)*, *Neuropathy (N)*, *Bacterial Infection (B)*, *Area (A)* and *Depth (D)*⁹. It is recommended by the *International Working Group on the Diabetic Foot (IWGDF)*² and considered useful for predicting ulcer complications and identifying cases most likely to require amputation⁹. Each assessment item receives a score of 0 or 1, depending on the absence or presence of changes or situations of greater severity, which leads to a total score ranging from zero to six.

Despite the advantages in evaluating ulcers², the SINBAD Classification System⁹ requires that its clinimetric properties are validated specifically for the population in which its use is proposed¹⁰. In this context, it is worth noting that its responsiveness has not yet been tested in any country.

Responsiveness is defined as the ability of an instrument to detect differences or changes in the construct being evaluated and can contribute to the evaluation of the effectiveness of a therapeutic intervention¹¹⁻¹².

Given the growth of diabetes mellitus in Brazil and foot complications, such as foot ulcers³, it is essential to analyze the responsiveness of the SINBAD Classification System⁹. Confirmation of this property will allow for the evaluation of changes in response to the therapeutic approach used during care and will assist the professional in decision-making in clinical practice. Furthermore, the use of the system may allow for the standardization of the assessment and its recording, enabling the identification of the conditions progression and injury severity over time.

By incorporating a responsive instrument into practice, healthcare professionals will be able to make decisions about the need to reformulate the therapeutic plan, perform frequent reassessments, and refer severe cases to referral services, reducing the risk of amputations. Therefore, the objective of this study was to analyze the responsiveness of the SINBAD Classification System in the evaluation of diabetes-mellitus-related foot ulcers.

METHOD

This is a clinimetric, longitudinal study, included in the multicenter Matrix project “Transcultural Adaptation of SINBAD System Classification for the Brazilian Portuguese, psychometric properties and test with the inclusion of new evaluation criteria (SINBAD 2.0)”. This survey was carried out between December 2023 and July 2024, in the following cities in Brazil: Goiânia-GO, Jataí-GO, Palmas-TO, Belo Horizonte-MG, and São Paulo-SP.

In these locations, reference centers for care for people with diabetes mellitus-related foot ulcers and Family Health Units were chosen as research scenarios. Thus, the study was carried out at the Chronic Wounds Outpatient Clinic of the *Hospital Estadual de Dermatologia Sanitária e Reabilitação Santa Marta* and at the State Diabetes Care Center of the *Hospital Estadual Dr. Alberto Rassi*, in Goiânia; at the Diabetic Foot Outpatient Clinic of the *Unidade de Referência Secundária Padre Eustáquio*, in Belo Horizonte; at the *Clinic Stay Care*, in São Paulo; and at the *Unidade Básica James Phillip Minelli*, in Jataí, which are reference services. In Tocantins, the study was carried out in Community Health Centers that make up the Family Health Unit. The frequency of care for ulcer treatment in the services varied, ranging from weekly to monthly, and by spontaneous demand.

The study population consisted of individuals with diabetes mellitus, receiving outpatient care in the research settings, with non-probabilistic convenience sampling.

Individuals aged 18 years or older and with a diabetes mellitus-related foot ulcer were included. To define a case of diabetes mellitus-related foot ulcer, the definition by the *International Working Group on the Diabetic Foot*² was considered.

The exclusion criteria were the presence of severe deafness and the unavailability of an interpreter for communication. Absence in assessments at 30 and 60 days or healing during this period were considered follow-up losses.

Recruitment of eligible individuals was carried out by researchers during routine care in the research settings. In some of these scenarios, the research team belonged to the group of professionals responsible for providing care, and in others, the researchers were present daily during the study period.

Those who agreed signed the Free and Informed Consent Form (FICF) and responded to a Participant Characterization Protocol with questions related to age, sex, time since diagnosis of diabetes mellitus (in years), and time since injury (in months). The instrument was developed by the authors and underwent a refinement process to verify if it met its purposes.

The first ulcer evaluation using the SINBAD Classification System⁹ occurred in the initial assessment (D_0), followed by reevaluations at 30 (D_{30}) and 60 days (D_{60}). The evaluation was carried out by researchers trained by the research coordinating center. They were specialists in Dermatological Nursing or Stomatherapy, master’s or doctoral students with projects developed in the area. All data were recorded on the platform *Research Electronic Data Capture – REDCap*¹³.

The version used in this investigation is the one culturally adapted to Brazilian Portuguese¹⁴. All items in the SINBAD system were evaluated according to the recommendations of the authors who originally developed the instrument⁹.

In the analysis of the item “Site”, the following scores were assigned: 0 for ulcers located in the forefoot and 1 for cases located in the midfoot or hindfoot. For the item “Ischemia”, 0 indicates the presence of at least one palpable pulse and absence of signs and/or symptoms of ischemia, while 1 indicates non-palpable pulses and/or the presence of signs or symptoms of ischemia. In the item “Neuropathy”, 0 refers to preserved protective sensitivity and 1 to impaired protective sensitivity. For the criterion “Wound infection”, 0 indicates absence and 1 indicates presence of infection. Regarding “Area”, 0 is assigned to ulcers less than 1 cm² and 1 to ulcers with an area greater than or equal to 1 cm². Finally, in the item “Depth”, 0 represents ulcers restricted to the skin and subcutaneous tissue,

while 1 corresponds to ulcers that reach muscle, tendon or deeper tissues. The total sum of scores can reach a maximum value of 6^{9,14}.

In reference services for care for people with diabetes mellitus-related foot ulcer, the initial and subsequent assessments took place on the same days scheduled for usual care. Professionals from the respective services removed the previous dressing and proceeded to clean the ulcer and, when necessary, performed debridement. The researchers then carried out the assessment using the SINBAD Classification System, which took between 5 and 10 minutes, depending on the edema conditions in the participants' legs, which made palpation more difficult. Soon after, the professionals resumed care and completed the remaining phases of the dressing. In health centers, follow-up visits to the unit were scheduled after 30 or 60 days had passed since the initial assessment.

Data organization and statistical analyses were performed using the software Statistical Package for Social Sciences (IBM SPSS Statistics for Windows, Version 29.0.2.0, Armonk, NY: IBM Corp.) and Microsoft Excel® for Microsoft 365 MSO (Version 2410 Build 16.0.18129.20100). Data normality was verified using the Shapiro-Wilk test, which showed that the distribution of the data was not normal.

Friedman's test, with p-value<0.05, was used to analyze the differences in ulcer areas between the three evaluation moments (D_0 - D_{30} - D_{60}). To identify when the difference occurred, pairwise analyses were performed (D_0 - D_{30} , D_0 - D_{60} and D_{30} - D_{60}). Cochran's Q test was used to compare the distribution of responses to nominal items in the SINBAD Classification System in the three intervals, with significance adjusted by the Bonferroni correction.

Using the Wilcoxon test, the difference between the total scores of the SINBAD Classification System in the intervals was analyzed: D_0 - D_{30} , D_0 - D_{60} and D_{30} - D_{60} . The effect size value was defined according to Cohen's classification for *r* 0.1 (small), 0.3 (moderate), 0.5 (large)¹⁵.

RESULTS

Initially, 113 individuals, totaling 120 diabetes mellitus-related foot ulcers were included in the study. Of these, 71 participants, totaling 77 ulcers, completed the assessments on days D_0 , D_{30} and D_{60} and were included in the responsiveness analysis.

Of the 71 participants in this section of the matrix study, 76.1% were male and 23.9% were female, aged between 23 and 80 years (median of 62 years). The median time since diagnosis of diabetes mellitus for these individuals was 15 years, while the median time since the diabetes mellitus-related foot ulcer was 12 months (Table 1).

Table 1 – Demographic and clinical characteristics of participants and diabetes mellitus-related foot ulcer, Brazil, Dec 2023/Jul 2024. (n=71)

Variable	M*	Q1 [†]	Q2 [‡]	Q3 [§]	IIQ
Age (years)	62	54	62	70	16
Time since diagnosis of diabetes mellitus (in years)	15	10	15	26	16
Time of diabetes mellitus-related foot ulcer (months)	12	03	12	26	23

Note: *M = Median; [†]Q1 = 1st quartile, [‡]Q2 = 2nd quartile, [§]Q3 = 3rd quartile, ^{||}IQR = Interquartile Range.

Among the 77 ulcers, the majority were located on the forefoot, without signs of infection, limited to the subcutaneous tissue and with an area $\geq 1\text{cm}^2$. The presence of neuropathy in 90.9% of participants (n=70) and signs of ischemia in 35.1% (n=27) in the initial evaluation stands out (D_0). When testing the responsiveness of the assessment items of the SINBAD Classification System, a significant difference was found in the proportions of responses to the items "Area" and "Depth" (Cochran's Q test; p<0.05), considering the period evaluated (Table 2).

Table 2 – Distribution of the proportions of responses to each item of the SINBAD Classification System in the intervals D_0 - D_{30} - D_{60} , obtained in the evaluation of diabetes mellitus-related foot ulcer, Brazil, Dec 2023/Jul 2024. (n=77)

Item		D_0^*		D_{30}^\dagger		D_{60}^\ddagger		p-value [§]
		<i>f</i>	%	<i>f</i>	%	<i>f</i>	%	
S Site	Forefoot	49	63.6	49	63.6	49	63.6	1
	Midfoot / Hindfoot	28	36.4	28	36.4	28	36.4	
I Ischemia	Foot with at least one palpable pulse and no signs and/or symptoms of ischemia	50	64.9	53	68.8	54	70.1	0.307
	Foot with non-palpable pulses and/or presence of signs or symptoms of ischemia	27	35.1	24	31.2	23	29.9	
N Neuropathy	Preserved protective sensitivity	7	9.1	4	5.2	5	6.5	0.097
	Impaired protective sensitivity	70	90.9	73	94.8	72	93.5	
B Bacterial Infection	Absent	61	79.2	63	81.8	69	89.6	0.104
	Present	16	20.8	14	18.2	8	10.4	
A Area	Ulcer < 1cm ²	29	37.7	37	48.1	43	55.8	<0.001
	Ulcer ≥ 1cm ²	48	62.3	40	51.9	34	44.2	
D Depth	Ulcer affects only the skin and subcutaneous tissue	46	59.7	51	66.2	55	71.4	0.047
	Ulcer affects muscle, tendon or deeper tissue	31	40.3	26	33.8	22	28.6	

Note: * D_0 = initial assessment, $^\dagger D_{30}$ = assessment on the 30th day, $^\ddagger D_{60}$ = assessment on the 60th day.
[§]Cochran's Q test; bold p-values <0.05, ^{||} *f* = frequency.

Comparing the distribution of each item individually in the different periods of interest, differences were observed only in relation to the area (S), between D₀ and D₆₀, and depth (D), between D₀ and D₆₀ (Table 3).

Table 3 – Comparisons between the distribution of the proportion of items from the SINBAD Classification System according to the observation interval, obtained in the assessment of diabetes mellitus-related foot ulcers, Brazil, Dec 2023/Jul 2024. (n=77)

Interval	S*	I†	N‡	B§	A	D¶
	p-value**	p-value	p-value	p-value	p-value	p-value
D ₀ – D ₃₀	1.000	0.804	0.472	1.000	0.085	0.513
D ₀ – D ₆₀	1.000	0.419	0.102	0.123	0.000	0.041
D ₃₀ – D ₆₀	1.000	1.000	1.000	0.376	0.301	0.820

Note: *S = Site; †I = Ischemia; ‡N = Neuropathy; §B = Bacterial Infection (wound infection); ||A = Area; ¶D = Depth. **Cochran's Q test (pairwise method); bold p-values <0.05.

The median area of ulcers reduced significantly in the time intervals (D₀: 1.9cm²; D₃₀: 1.17cm²; D₆₀: 0.6cm²). There was a significant difference (p<0.001) in the ulcer area at all intervals (D₀-D₃₀, D₀-D₆₀ and D₃₀-D₆₀) (Table 4).

Table 4 – Comparison of ulcer area distributions in D₀-D₃₀, D₀-D₆₀ and D₃₀-D₆₀, obtained in the evaluation of diabetes mellitus-related foot ulcers, Brazil, Dec 2023 / Jul 2024. (n=77)

Comparison period	Median ulcer area in cm ²	p-value *
D ₀ -D ₃₀	1.9 – 1.17	<0.001
D ₀ -D ₆₀	1.9 – 0.6	<0.001
D ₃₀ -D ₆₀	1.17 – 0.6	0.004

* Friedman test; bold p-values <0.05.

The median of the “Total possible score” of the SINBAD System was 3 in the initial assessment (D₀) and 2 in the D₃₀ and D₆₀ assessments, and the maximum value decreased from 6 to 5 only in D₆₀. Significant differences in the “Total Possible Score” of the SINBAD Classification System were found in D₀-D₆₀ and D₃₀-D₆₀, both with effect size $r = 0.436$ and $r = 0.333$, respectively (Table 5).

Table 5 – Descriptive measures and comparison of the total score obtained in the SINBAD Classification System in the evaluation of diabetes mellitus-related foot ulcers in the intervals D₀-D₃₀, D₀-D₆₀ and D₃₀-D₆₀, and respective effect size, Brazil, Dec 2023/Jul 2024. (n=77)

Variables	M*	IIQ†	MIN‡	MAX§	Z value	p value¶	Effect size r**
Total score D ₀	3	2.0-4.0	1	6	1.608	0.108	0.183
Total score D ₃₀	2	1.0-4.0	1	6	3.825	<0.001	0.436
Total score D ₆₀	2	1.0-4.0	1	5	2.92	0.004	0.333

Nota: *M = median. †IIQ = Interquartile range; ‡MIN = minimum; §MAX = maximum; ||Z value = standardized value. ¶Wilcoxon test; bold p-values <0.05. **Effect size based on Cohen's guidelines to r . The Effect Size was calculated by comparing the total scores at each time interval, that is, between D₀ and D₃₀, D₀ and D₆₀, and D₃₀ and D₆₀ respectively.

DISCUSSION

This study was a pioneer in evaluating the responsiveness of the SINBAD Classification System in the evaluation of diabetes mellitus-related foot ulcers.

No item or overall score showed significant changes between D_0 and D_{30} . This suggests that the system may not detect clinical changes in this time interval. However, the system is useful for communication between healthcare professionals, audits, research and local developments, allowing comparison of injury severity among different care centers. Studies in new scenarios should be carried out to corroborate or refute the lack of responsiveness between the first assessment and the 30-day assessment (D_0 - D_{30}).

The System allows detecting changes between D_0 and D_{60} , D_{30} and D_{60} . Furthermore, among its evaluation items, a significant change was found in relation to area and depth, between D_0 and D_{60} . This indicates that the system is capable of detecting small, clinically relevant changes over a longer follow-up period, being more effective in monitoring the response to topical treatment over longer periods, indicating significant changes in the items "Area" and "Depth".

There are several purposes of use and desirable clinimetric properties for a measuring instrument. The latter are not static and may vary depending on the application scenario; therefore, there is a need to measure them in different contexts. The results of this investigation add to other information available on the SINBAD Classification System, among which the good sensitivity and specificity for complications such as amputation stand out¹⁶⁻¹⁸, being useful in clinical practice for this purpose. Therefore, its use should be encouraged.

Because the study was carried out in five cities in four Brazilian states, in the North, Central West and Southeast regions, common epidemiological characteristics of people with diabetes mellitus stand out. Among the participants, 76.1% were male and the median age was 62 years old. The greater predominance of diabetes mellitus-related foot ulcers in men and the greater incidence in people aged 60 years or older are recurring findings in national and international studies¹⁹⁻²¹.

The long time since the diagnosis of diabetes mellitus among the participants is justified by the fact that chronic ulcers, resulting from neuropathy and/or ischemia, were identified in a context of late diagnosis or high glycemic variability and hyperglycemia²².

The high median duration of foot ulcers can be attributed to delayed healing due to the disease and difficulty in clinical adherence and blood glucose control, in addition to obstacles to access health services, and the absence of rehabilitation measures such as therapies to relieve plantar pressure areas – offloading and specific orthotization²³⁻²⁴.

The score for ulcer "Site" obviously remained stable, indicating that neuropathic ulcers are predominantly located in the metatarsal regions of the forefoot. When evaluating ulcers, it is crucial to identify the injured anatomical area due to the predictive possibility of complications arising from them, especially ischemic ones, which are mostly located in the hindfoot and significantly impact survival among those affected²⁵.

In this study, the items of the SINBAD Classification System related to systemic conditions, such as "Neuropathy" and "Ischemia", did not vary significantly in the time interval analyzed.

Several factors interfere with the clinical history of ulcerations, such as general health status, glycemic variability, peripheral perfusion, decreased mobility, and increased risk of serious complications, such as sepsis and renal failure²⁵. Neuropathy is an early complication in people with diabetes mellitus, resulting in sensory, motor or autonomic dysfunction and loss of protective sensitivity and, once established, is usually irreversible²⁶. Ischemia, associated with macrovascular and microvascular diseases, leads to low blood perfusion, worsening outcomes, including lower healing rates, longer healing times, ulcer recurrence, and increased risk of amputations²⁷.

Palpation of the pulses (posterior tibial, dorsalis pedis, popliteal, and superficial femoral) of the affected lower limb is central to the vascular examination, but requires skill and practice². Revascularization to restore blood flow has been recognized as an alternative for ulcer healing and is related to greater survival of individuals with diabetes mellitus-related foot ulcers².

For “Wound infection” there was no significant difference in responses throughout the period evaluated. In the present study, the participants were receiving outpatient care, and the ulcers were predominantly superficial, which may explain the low incidence of infection, which remained throughout the period, leading to a lack of responsiveness in this regard.

Factors that predispose to foot infection in people with diabetes mellitus include: a deep, long-standing, recurrent ulcer, a compromised immune response related to diabetes mellitus, or the presence of chronic renal failure².

A detailed inspection of the ulcer is essential to identify infections and initiate appropriate treatment; in diabetes mellitus, foot ulcers have a 56 times greater risk of hospitalization and a 154 times greater risk of amputation²⁸.

It is important to note that people with diabetes mellitus do not present typical signs of serious infections due to an impaired immune response²⁹; therefore, attention should remain focused on identifying subclinical signs, such as discoloration in the granulation tissue.

The items “Area” and “Depth” showed significant changes, with most ulcers reducing in size at intervals during the assessment. Measuring the ulcer area is important to assess the response to topical therapy, and re-evaluation of treatment is recommended if there is no 50% reduction in the area within the first four weeks³⁰.

Determining the depth of a diabetes mellitus-related foot ulcer can be challenging, especially in the presence of tylosis or callus and necrotic tissue. For an accurate assessment, specific intervention is necessary by removing hyperkeratosis or hemorrhagic calluses, except in the presence of signs of severe ischemia². The depth of the ulcer must be checked and classified appropriately after each intervention.

As healing progresses, the depth of ulcers is expected to reduce significantly,¹⁸ which may justify the responsiveness result of this assessment item in the present study.

The SINBAD Classification is used after a detailed physical examination. The score obtained by adding the scores obtained in the evaluation of important data about the ulcer contributes to communication between health professionals. The description of the lesion evaluated is important. Extra care must be taken when monitoring cases in which ulcers reach deeper tissues, due to the risk of osteomyelitis, an extremely serious condition that leads to many complications.

Although the research contributed to a thorough evaluation of diabetes mellitus-related foot ulcers and expanded the horizons of available knowledge on the clinimetric properties of the SINBAD System Classification, some limitations should be considered. Among them, the non-probabilistic convenience sampling, the predominance of superficial ulcers and, despite being a multicenter study, the inclusion of only four of the 26 Brazilian states stand out.

The absence of planigraphy for precise determination of the ulcer area and the failure to perform the ankle-brachial index or arteriography with duplex scan for the evaluation of changes in arterial flow cannot be considered limitations, since the SINBAD System was evaluated for its responsiveness and not for the accuracy of the measurement.

CONCLUSION

There is evidence of responsiveness of the SINBAD Classification System between the first assessment and the 60-day assessment, and between the second assessment and the 60-day assessment, with a moderate effect size. Standardized assessment through this system can help

assess response to treatment and systematically identify cases that need to be referred to reference services. Nursing training to use this system, especially for those working in Primary Health Care, should be included in the planning of continuing health education, in addition to establishing the adoption of this tool in public policies, contributing to the reduction of complications and future amputations.

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NOTES

ORIGIN OF THE ARTICLE

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CONTRIBUTION OF AUTHORITY

Study design: Barros LS, Bachion MM, Martins MA, Borges EL, Gamba MA, Malaquias SG.

Data collection: Barros LS, Dias JL, Torres DM, Pereira AL, Malaquias SG, Nunes CAB, Neto MGS, Martins MA.

Data analysis and interpretation: Bachion MM, Barros LS, Malaquias SG, Nunes CAB, Neto MGS, Martins MA.

Discussion of results: Barros LS, Bachion MM, Dias JL, Torres DM, Borges EL, Pereira AL, Malaquias SG, Nunes CAB, Neto MGS, Martins MA, Gamba MA.

Writing and/or critical review of content: Barros LS, Bachion MM, Dias JL, Torres DM, Borges EL, Pereira AL, Malaquias SG, Nunes CAB, Neto MGS, Martins MA, Gamba MA.

Review and final approval of the final version: Barros LS, Bachion MM, Dias JL, Torres DM, Borges EL, Pereira AL, Malaquias SG, Nunes CAB, Neto MGS, Martins MA, Gamba MA.

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CONFLICT OF INTEREST

The authors declare there are no conflicts of interest.

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DATA AVAILABILITY

The data supporting the conclusions of this study are available from the corresponding author upon reasonable request.

CORRESPONDING AUTHOR

Luciana da Silva Barros.

lubarros2705@gmail.com

