

Clinical evaluation instruments for leg ulcers

Instrumentos de avaliação clínica para úlceras de perna

Beatriz Guitton Renaud Baptista de Oliveira¹ • Joana Aragão da Silva² • Isabelle Andrade Silveira³
• Nathalia Caldas Santos⁴ • Magali Rezende de Carvalho⁵

RESUMO

Objetiva-se analisar os instrumentos/escalas de avaliação clínica para úlceras de perna disponíveis na literatura. Trata-se de uma revisão integrativa nas bases: PubMed/Medline, CINAHL, SCOPUS e LILACS. Foram considerados estudos que utilizaram instrumentos valorados e avaliados clinicamente pelo profissional sem utilização de outras tecnologias. Não foi estabelecido recorte temporal e restrição de idiomas. Foram analisados 12 estudos, totalizando 10 instrumentos/escalas (3 estudos discorriam sobre o mesmo instrumento). Os parâmetros/itens dos instrumentos avaliados têm concordância de 50% em relação à área, profundidade, tecido, exsudato e infecção. Outros itens observados foram: dor, presença de tecido necrótico, borda da ferida e edema. Conclui-se que os instrumentos/escalas apontam concordância em relação à avaliação do tamanho da lesão, aspecto e infecção, entretanto, divergem em outros pontos. Cabe ao profissional identificar o que mais atende ao perfil da população alvo e a disponibilidade para uso em seu país.

Palavras-chave: Escalas; Instrumentos; Feridas; Úlcera da Perna; Úlcera do Pé.

ABSTRACT

This research aims to analyze the instruments/clinical assessment scales for leg ulcers available in the literature. This is an integrative review study in the databases: PubMed/Medline, CINAHL, SCOPUS e LILACS. Were included studies that used instruments valued and evaluated clinically by the professional without the use of other technologies. No temporal clipping and language restriction were established. Twelve studies were analyzed, totaling 10 instruments/scales (3 studies were based on the same instrument). The parameters/items of the evaluated instruments have a 50% agreement regarding: area, depth, tissue, exudate and infection. Other items observed were: pain, presence of necrotic tissue, wound border and edema. It concludes that the instruments/scales show agreement regarding the evaluation of lesion size, appearance and infection, however they differ in other points. It is up to the professional to identify what most suits the profile of the target population, in addition to what is available for use in their country.

Keywords: Scales; Instruments; Wounds; Leg Ulcer; Foot Ulcer.

NOTA

¹Enfermeira Doutora em Enfermagem. Professora titular e coordenadora do Programa Acadêmico em Ciências do Cuidado em Saúde (PACCS) da Escola de Enfermagem Aurora de Afonso Costa da Universidade Federal Fluminense. (EEAAC/UFF). Niterói/Brasil.

²Enfermeira. Mestranda do Programa Mestrado Profissional em Enfermagem Assistencial (MPEA) da Escola de Enfermagem Aurora de Afonso Costa da Universidade Federal Fluminense (EEAAC/UFF). Niterói/ Brasil. E-mail: joanaenfe@gmail.com.

³Enfermeira. Doutoranda do Programa Acadêmico em Ciências do Cuidado em Saúde (PACCS) da Escola de Enfermagem Aurora de Afonso Costa da Universidade Federal Fluminense (EEAAC/UFF). Niterói/ Brasil. E-mail: isabelleandradesilveira@gmail.com.

⁴Acadêmica em Enfermagem da Escola de Enfermagem Aurora de Afonso Costa da Universidade Federal Fluminense (EEAAC/UFF). Niterói/ Brasil.

⁵Enfermeira estomaterapeuta. Mestre em Ciências do Cuidado em Saúde pela EEAAC/UFF. Niterói/Brasil.



INTRODUCTION

Leg ulcers stand out among chronic wounds of worldwide importance and affect from 1% to 2% of the population worldwide ⁽¹⁾. It can be defined as “any damage to the skin below the knee that takes more than 04 weeks to heal” ^(2:41).

Leg ulcers can be categorized into three predominant etiologies. Venous ulcers represent the most advanced stage of chronic venous insufficiency and its prevalence ranges from 0.12% to 2.4% of the world population ⁽³⁾. Arterial ulcers are less common and responsible for about 20% of leg ulcers ⁽⁴⁾. Lower extremity wounds occur in about 15% to 25% of patients with diabetes ⁽⁵⁾.

Ulcers are often evaluated and treated in an unsystematic and inappropriate manner. For the nurse to treat patients with leg ulcers, it is necessary to understand the tissue repair process, besides knowing the clinical and histopathological characteristics of ulcers ⁽⁶⁻⁷⁾.

Chronic wound management involves periodic evaluation and the use of reliable and validated instruments can improve communication among professionals, defining a common language and standardizing assessment ⁽⁸⁾. In addition, it is critical that the patient be involved in their treatment and has a feedback about the therapy adopted.

Assessment tools assist nurses in wound management, and many have been developed for this purpose. However, there is a lack of consensus as to which should be adopted to provide a consistent assessment ⁽⁹⁾. In this context, the objective of this review was to analyze the instruments / clinical assessment scales for leg ulcers available in the literature.

METHOD

This is an integrative review of literature, whose research question elaborated according to the PICo (10) strategy was thus determined: Which clinical assessment scales / instruments for leg ulcers are available in the literature?

The research took place on 06/13/2018 in the following databases: PubMed / Medline; CINAHL Plus with Full Text, SCOPUS and LILACS. Thesauri MeSH, DeCs and Cinahl Titles, as well as free terms, were rescued for the construction of specific search strategies for each database. Boolean operators AND and OR were combined.

We included studies that used assessment scales / instruments clinically evaluated by the professional without the use of other technologies. And excluded studies evaluating pressure injuries, quality of life alone, risk of developing leg ulcers, editorials, letters to the editor, literature reviews, theses and congress summaries. No temporal clipping and language restriction were established.

Search strategy for PubMed: (((((((scales[Text Word])

OR measurement tool[Text Word]) OR assessment tool[Text Word]) OR tool[Text Word]) OR assessment scale[Text Word]) OR wound assessment[Text Word])) AND (((((((((((leg ulcer[Text Word]) OR leg ulcers[-Text Word]) OR leg ulceration[Text Word]) OR varicose ulcer[Text Word]) OR venous ulcer[Text Word]) OR venous leg ulcer[Text Word]) OR arterial ulcers[-Text Word]) OR arterial ulcer[Text Word]) OR diabetic foot[Text Word]) OR foot ulcers[Text Word]) OR diabetic foot ulcer[Text Word]).

For the search in the other databases, the adaptations of the search strategy described above were used according to the specificities of each database.

After exclusion of the duplicates, the studies were analyzed in relation to the title and abstract. The relevant studies were rescued in full and the eligibility criteria applied. Then, an analytical reading was performed. The presentation of the results and discussion of the data obtained was done in a descriptive way and for the analysis, the thematic categorization was chosen.

RESULTS

A total of 1,503 studies were retrieved, after exclusion of the duplicates and application of the eligibility criteria, 12 articles were included in this review, as shown in the flowchart (Figure 1).

Twelve studies were analyzed, totaling 10 instruments / scales (3 studies were based on the same instrument). The instruments / scales were: Leg Ulcer Measurement Tool (LUMT), Diabetic Foot Ulcer Assessment Scale (DFUAS), A Prognostic Score Estimating Probability of Healing in Chronic Lower Extremity Wounds (MAID), Severity Scale for Wound-healing Prognosis, Classification System and Score in Comparing Outcome of Foot Ulcer Management (SINBAD), Wound bed score (WBS), The Wound Trend Scale (WTS), A New Wound-Based Severity Score for Diabetic Foot Ulcers (DUSS), Development of a wound healing index for chronic wounds (RESVECH), Pressure Ulcer Scale for Healing (PUSH).

The studies that compose the final sample (Figure 2) were published between 2002 and 2016. All were aimed at developing, testing and / or validating clinical assessment tools (scales) for leg ulcers. There was no concentration of the publications in a specific year, evidencing, then, that over the years the interest for the theme remains constant. This fact can perhaps be attributed to the precariousness and even absence of instruments considered gold standard over the years. There was no concentration of the publications in a specific periodical. However, 10 studies were published in American journals, of which, 7 journals were scoped with a focus on dermatology.

Regarding the type of study, there were predominant

instruments based on prospective cohorts (7), followed by methodological studies (3) and retrospective analyzes of other studies (2). More than 4,000 patients and more than 5,000 lesions were evaluated.

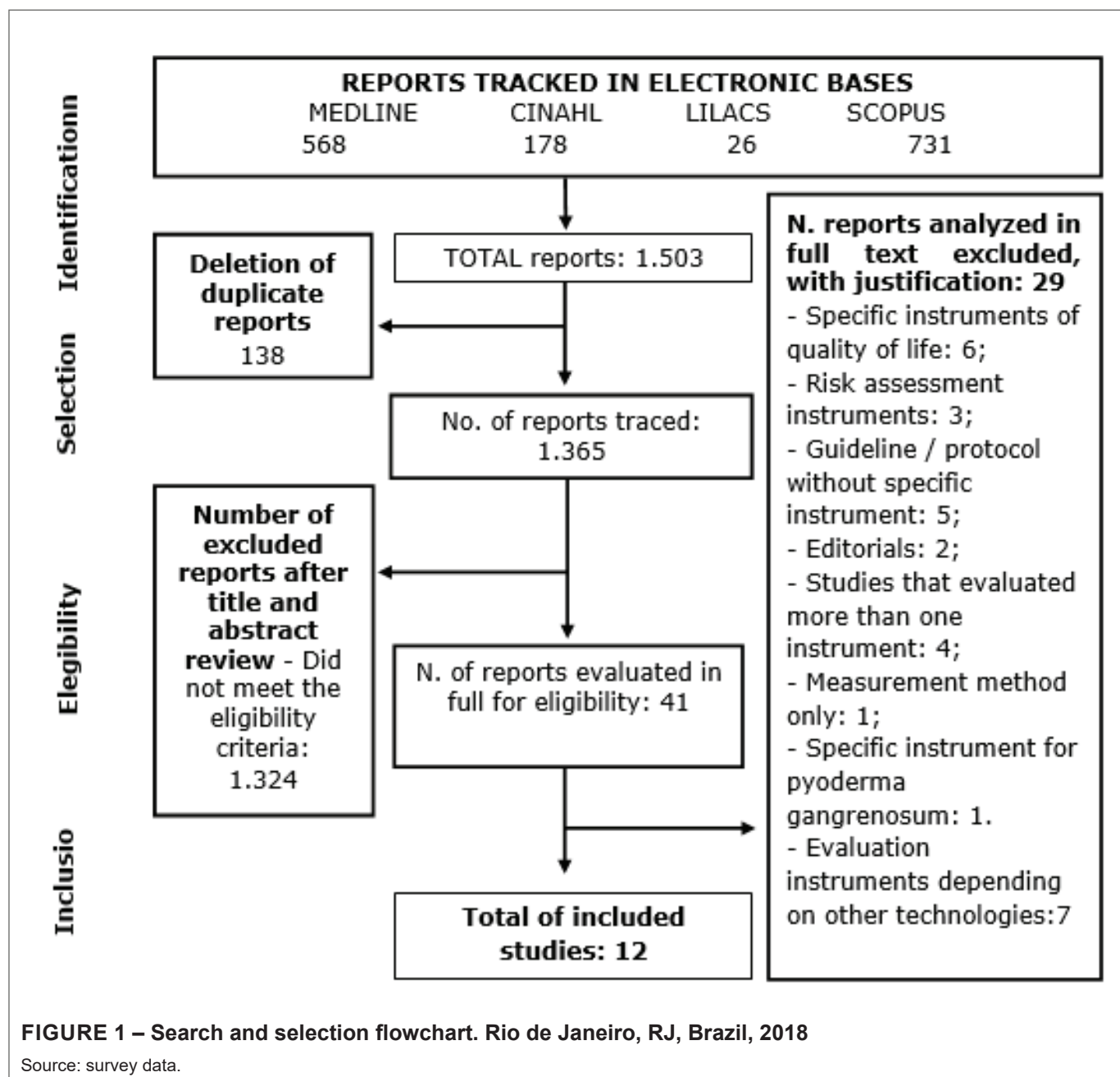
The tools had different evaluated items / parameters and the content of the items was also quite diverse. Three instruments for diabetic ulcer, six were for leg ulcers in general and one specific for venous ulcer. The instruments were submitted to statistical procedures in order to ensure their validity. Figure 3 presents the characterization of the instruments / scales included in this study.

DISCUSSÃO

The discussion of the studies was carried out in two categories: "Evaluation tools for leg ulcers according to etiology" and "Items evaluated in the instruments".

Among the included studies, some instruments were developed and applied in leg ulcers independent of etiology: PUSH, LUMT, WTS, WBS, MAID and RESVECH.

Three studies evaluated the Pressure Ulcer Scale for Healing (PUSH). One analyzed its viability for venous ulcers and identified that PUSH scores decrease significantly over time⁽²⁰⁾. In another, the interobserver reliability was confirmed by the Kappa index⁽¹⁹⁾. One evaluated the scale in diabetic ulcers and identified a predictive value for healing⁽¹⁸⁾. A comparison of the results for venous ulcers with the traditional clinical evaluation pointed out that, although it is a scale of easy application, it is faulty to evaluate certain lesions⁽²¹⁾. In 47% of the ulcers with scores that indicated no change, according to PUSH, they were evaluated as "improved" by the nurses. Despite this, PUSH's responsiveness to leg ulcers can be confirmed⁽²²⁾.



Instruments	Objectives	Method	Results
LUMT ⁽¹¹⁾	Develop and validate an assessment instrument, the Leg Ulcer Measurement Tool, capable of detecting changes in the appearance of leg ulcers.	Methodological study. N = 22 subjects with leg ulcer and for reliability N = 4 wound specialists and 2 inexperienced evaluators.	Validity of content was confirmed by 9 experts. The competing criterion was (r 0.82). The intra and interrater reliability (ICC > 0.75). The coefficient of responsiveness = 0.84).
DFUAS ⁽⁸⁾	Develop and validate a specific assessment tool for diabetic foot ulcer in Indonesia.	Prospective cohort. N = 62 patients with 70 diabetic foot ulcers.	The scores were: concurrent validity (0.92), construct validity (0.87) and predictive validity (0.82). The comparison of the DFUAS total score with the chronic wound condition was <0.001.
MAID ⁽¹²⁾	To evaluate a prognostic score for leg ulcers with a predictive value for healing.	Prospective cohort. N = 2019 patients, with 4,004 wounds were included.	There was a 84% cure probability for uncomplicated ulcers, decreasing to 31% for ulcers with muscle impairment. Cox regression was used to show the correlation between MAID and cure.
Severity Scale for Wound-healing Prognosis ⁽¹³⁾	Construct a user-friendly severity scale with predictive value for healing.	Retrospective analysis of data from a prospective, randomized, controlled study. N = 240 patients with venous ulcers.	Among severe venous ulcers, 48% of patients treated with compression therapy achieved complete wound closure at 6 months, compared with 19% of patients treated with control.
SINBAD ⁽¹⁴⁾	Create a simplified version of the S(AD) SAD classification.	Cohort. N = 449 patients with diabetic foot ulcers.	It was identified that the SINBAD has a predictive value for healing.
WBS ⁽¹⁵⁾	Develop and test a new classification system for the wound bed with predictive value.	Prospective study based on an ECR. N = 177 patients with venous ulcers.	The percentage of healed wounds correlated with WBS. An increase of one unit in total WBS resulted in an average of 22.8% in the chances of healing.
WTS ⁽²⁾	Provide an assessment tool that supports nurses to assess wounds and identify early risks.	Retrospective study from a random sampling of medical records. N = 70 patient records.	The predictive values of healing were sensitivity (99%), specificity (87%). Inter- and intra-observer reliability was 0.85 and 0.86, respectively.
DUSS ⁽¹⁶⁾	Develop a clinical scoring system for diabetic ulcers capable of estimating healing and amputation risks.	Prospective cohort. N = 1,000 patients.	Cox regression model confirmed a high correlation between the severity score and the healing time, resulting in a risk ratio of 0.648 (95%, P 0.001).
RESVECH ⁽¹⁷⁾	Develop a scale to measure the progress of healing in chronic ulcers.	Two-phase study. Phase I: systematic review. N = 20 articles. Phase II: Modified Delphi study for development of the RESVECH scale.	Used modified Delphi method to get the Content Validity Index (IVC) value, with score above 0.80 for all items that make up the scale.
PUSH ⁽¹⁸⁻²⁰⁾	To examine the predictive validity of PUSH 3.0 in monitoring the healing of neuropathic ulcers in patients with diabetes mellitus.	Descriptive prospective study. N = 18 subjects.	Reduction of 53% in the wound area at 4 weeks of follow-up predicted that the wound would heal in 12 weeks.
	To test the interobserver reliability of PUSH in the Portuguese adapted version in patients with chronic leg ulcers.	Methodological study. N = 30 injuries Nurses: 4 stomatologists and 3 clinics.	Kappa indexes obtained (0.97 to 1.00), attested the interobserver reliability, with very good agreement to total for all subscales and total PUSH score.
	To explore the feasibility of using the PUSH tool to evaluate healing in patients with venous ulcers.	Descriptive prospective study. N = 27 patients with venous ulcers.	23 patients had a decrease in the PUSH score in the 02-month period; of these, 04 had PUSH scores of zero at 02 months because their venous ulcers had healed.

FIGURE 2 – Characterization of the studies. Rio de Janeiro, RJ, Brazil, 2018

Source: research data.

Instruments	Nº and questions	Content of items	Validation
LUMT ⁽¹¹⁾	Composed of 2 parts. The first one with 14 items evaluated clinically and the second with 3 items answered by the patient. The 1st score varies from 0 to 56 points, where 0 indicates that the wound has closed. The 2nd score ranges from 0 to 12 and the closer to 12, the worse the pain and the quality of life.	1st part evaluates: type and amount of exudate, wound size and depth, type and amount of necrotic tissue and granulation, borders, adjacent skin, type and location of edema and presence of infection. 2nd part evaluates the intensity and frequency of pain and quality of life.	Validity of content; Validity of Criterion; Reliability and Responsiveness.
DFUAS ⁽⁹⁾	It has 11 domains on a scale of 0 and 98. Higher indices indicate more severe wounds.	Depth, size, size scores, inflammation / infection, proportion of granulation tissue, necrotic tissue (3 subitems are evaluated in this domain), maceration, wound border type and tunneling.	Concurrent validity, construct validity and predictive validity.
MAID ⁽¹²⁾	Score with 4 parameters clinically evaluated. The score ranges from 0 to 4 and the closer to 4, the worse the condition of the wound.	Presence of pediatric pulse, wound area, duration of ulcer and presence of multiple ulcers.	Multivariate regression analysis to correlate the evaluated parameters with the probability of cicatrization.
Severity Scale for Wound-healing Prognosis ⁽¹³⁾	5 parameters are evaluated, 4 the maximum score is 2. In 1, the maximum score is 4. The possible scores range from 5 (mild severity) to 12 (more severe).	Initial area, duration of ulcer, IAET stages (depth) of the ulcer, presence of fibrin in the wound bed and localization of the ulcer.	To validate the severity scale, multivariate regression analysis was performed to verify the weighted scores assigned to each parameter on the scale.
SINBAD ⁽¹⁴⁾	6 categories are evaluated, each category generates a score of 0 or 1. The closer to 6, the worse the healing and the lower the probability of healing.	Local, ischemia, neuropathy, bacterial infection, area and depth.	Univariate analyzes and multivariate analysis were performed by logistic regression.
WBS ⁽¹⁵⁾	8 parameters score from 0 (worst score) to 2 (best score). Each wound can have a maximum score of 16 (best state) at 0 (worst state).	Edge of the wound; necrosis; greater depth of wound; granulation tissue; amount of exudate; edema; dermatitis, callosity or fibrosis around the wound and wound bed pink or red.	Univariate analyzes and multivariate analysis by logistic regression.
WTS ⁽²⁾	14 parameters. In each parameter, a value is assigned (varied between them) that corresponds to its potential for impairment to healing. The total score is the combination of influences of each parameter.	Area, depth, border, detachment, necrotic tissue, amount of exudate, skin perilesion, edema, induration, granulation, epithelization, total WTS, infection and scarring.	Calculated predictive value and reliability.
DUSS ⁽¹⁶⁾	Score with 4 clinically evaluated parameters. The score ranges from 0 to 4 and the closer to 4, the worse the condition of the wound.	Presence of pediatric pulse, bone exposure / tunneling, wound site, number of ulcers.	The parameters that influence healing were calculated with multivariate analysis and logistic regression.
RESVECH ⁽¹⁷⁾	The scale is numerically marked and has a score ranging from 0 to 40 points. The higher the score, the worse the condition of the wound.	Wound dimensions, depth / tissues involved, borders, perilesional maceration, tunneling, tissue type of the wound bed, exudate, infection and pain frequency.	Content Validity by the Delphi technique.
PUSH ⁽¹⁸⁻²⁰⁾	03 parameters are evaluated. Each one has subscores that add up to between 0 and 17, with larger total scores indicating worse injury conditions.	Wound area in cm ² (score 0-10), amount of exudate present in the wound (0-3 points), wound bed appearance (0-4).	Multivariate and logistic regression analysis. Interobserver reliability. Interobserver reliability.

FIGURE 3 – Characterization of instruments / scales. Rio de Janeiro, RJ, Brazil, 2018.

Source: research data.



The Leg Ulcer Measurement Tool (LUMT) ⁽¹¹⁾ was developed in Canada with a reliability > 0.75 for LUMT score and total responsiveness. Recommended for evaluation of venous ulcers ⁽²³⁾, although there is still a need for validation with a more comprehensive method, since the categories of response cover only small lesions ⁽²⁴⁾.

The Wound Trend Scale (WTS) was created with the aim of providing a systematic assessment tool that identified risks of worsening early. The WTS achieved sensitivity (99%), specificity (87%), positive predictive value (96%), negative predictive value (96%) and test efficiency (96%). The WTS represents a specific instrument irrespective of the healing potential, with the large difference between LUMT and WTS being the wound area score and its interpretation in the total score, since the intervals assigned in the LUMT are smaller and even the lesions having decreased may continue punctuating score 4 in that item (maximum value) ⁽²⁾.

The Wound Bed Score (WBS) ⁽¹⁵⁾ is a classification system for wound bed evaluation that shows a strong correlation between total WBS and shorter wound healing time. When the logistic regression was used for total WBS, a predictive value was obtained for complete wound healing.

The chronic lower limb ulcer score (MAID) ⁽¹²⁾ has four clinically evaluable parameters and helps predict long-term clinical outcome. Predictive value of area and duration of wound healing was demonstrated for venous, diabetic, and arterial ulcers. Correlation between the quality of life of patients with venous ulcers and wound severity was determined using the MAID, highlighting its limited descriptive capacity, but the use is easy and practical ⁽²⁵⁾.

The Wound Healing Index for Chronic Wounds (RES-VECH) ⁽¹⁷⁾ was developed to measure the healing process of chronic ulcers and submitted to content validity by specialists, demonstrating clarity and ease of comprehension. It was possible to identify the existence of a clear relation between the quality of life and the total score of the instrument ⁽²⁵⁾.

Other instruments were developed and applied exclusively for diabetic ulcers: DFUAS, SINBAD and DUSS.

The Diabetic Foot Ulcer Assessment Scale (DFUAS) was developed to assess diabetic ulcers and predict healing. DFUAS can predict wound healing in 4 weeks and relationships with external criteria (BWAT, PUSH and superficial wound area) showed excellent correlations ⁽⁸⁾.

The objective of this study was to create a simpler version of S(AD) SAD classification in which the original 5 elements (area, depth, infection, ischemia and neuropathy) were retained and the structure simplified by reduction of subgroups to 2. It was observed that different

ulcer characteristics are associated with the result in different countries ⁽¹⁴⁾ and that these characteristics can be expressed in an aggregated SINBAD score ⁽²⁶⁾.

The New Wound-Based Severity Score for Diabetic Foot Ulcers (DUSS) is a clinical scoring system for assessing severity of diabetic ulcers. It showed a decreasing likelihood of healing for ulcers with elevated DUSS, with increased amputation rates. DUSS categorizes different ulcers into subgroups with specific severity and similar clinical outcome. Using this score, the odds of healing, amputation, need for surgery, and hospitalization are predictable with high accuracy ⁽²⁶⁾.

Only one instrument was specifically for venous ulcers. The Severity Scale for Wound-healing Prognosis ⁽¹³⁾ predicts venous ulcers with chances of healing, including evaluation of duration, location, area, depth and presence of fibrin. Ulcers with scores of 5 to 8 were classified as "mild or moderate severity" and 9 to 12 as "severe". The scale can be used to identify unlikely ulcers to respond to standard compressive therapy treatment.

The parameters / items varied between the studies. Each assigned different scores and included different analyzes. However, some items were included in at least 50% of the studies: wound area (in 8 instruments), depth (7), tissue type (7), exudate (5) and infection (5). The parameters that evaluated the venous ulcers are the same as the other ulcers. However, specific instruments to assess diabetic ulcers included wound site, tunneling, ischemia, neuropathy and presence of pediatric pulse.

The area is defined as the measurement of wound size that provides an idea of tissue loss. Adequate measurement is useful for comparing changes over time ⁽²⁷⁻²⁸⁾. These measures provide accurate information to health professionals, allowing better assessment and monitoring of injuries ⁽²⁹⁾. Regarding depth, wounds can be classified into superficial, partial and total thickness ⁽³⁰⁾.

The tissue type reflects the healing stage of the wound ⁽⁹⁾. It may be from necrosis, granulation or epithelialization and yet present itself as a combination of some or all of these. Proper identification directs treatment and the percentage should be estimated and documented. The evaluation of exudate is one of the most important aspects and identifies underlying problems: infection, patient satisfaction and therapy selection. The nature, quantity, odor and consistency types should be evaluated ⁽³⁰⁾.

Regarding signs of infection, all wounds are contaminated to varying degrees. The classic signs of infection are: pain, heat, flushing and edema. However, these may not be obvious and additional criteria are identified, such as delayed healing, discoloration, friable granulation tissue, unexpected pain, increased exudate, abnormal odor, fistula ⁽³⁰⁾.

CONCLUSION

This research aimed to analyze clinical assessment instruments for leg ulcers including 12 studies, totaling 10 instruments / scales. All the instruments were submitted to statistical treatment of applicability with diverse validation forms. The parameters / items evaluated varied with different scores, however, some items were included in at

least 50% of the studies, namely: wound area, depth, tissue type, exudate and infection. Given the diversity of the instruments beyond their contents and the validity for the practice, it is not possible to establish a recommendation of the most appropriate, useful and valid. It is up to the professional to identify what serves the target population, besides what is available for use in their language.

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