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Guidelines on the classification of diabetic foot ulcers (IWGDF 2019)

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Abstract

The International Working Group on the Diabetic Foot (IWGDF) has been publishing evidence-based guidelines on the prevention and management of diabetic foot disease since 1999. This publication represents a new guideline addressing the use of classifications of diabetic foot ulcers in routine clinical practice and reviews those which have been published. We only consider systems of classification used for active diabetic foot ulcers and do not include those that might be used to define risk of future ulceration.

The guidelines are based on a review of the available literature and on expert opinion leading to the identification of eight key factors judged to contribute most to clinical outcomes. Classifications are graded on the number of key factors included as well as on internal and external validation and the use for which a classification is intended.

Key factors judged to contribute to the scoring of classifications are of three types: *patient related* (end-stage renal failure), *limb-related* (peripheral artery disease and loss of protective sensation), and *ulcer-related* (area, depth, site, single, or multiple and infection). Particular systems considered for each of the following five clinical situations: (a) communication among health professionals, (b) predicting the outcome of an individual ulcer, (c) as an aid to clinical decision-making for an individual case, (d) assessment of a wound, with/without infection, and peripheral artery disease (assessment of perfusion and potential benefit from revascularisation), and (d) audit of outcome in local, regional, or national populations.

We recommend: (a) for communication among health professionals the use of the SINBAD system (that includes Site, Ischaemia, Neuropathy, Bacterial Infection and Depth); (b) no existing classification for predicting outcome of an individual ulcer; (c) the Infectious Diseases Society of America/IWGDF (IDSA/IWGDF) classification for assessment of infection; (d) the WIfI (Wound, Ischemia, and foot Infection) system for the assessment of perfusion and the likely benefit of revascularisation; and (e) the SINBAD classification for the audit of outcome of populations.

KEYWORDS

classification, diabetic foot, foot ulcer, guidelines

RECOMMENDATIONS

1. In a person with diabetes and a foot ulcer, use the SINBAD system for communication among health professionals about the characteristics of the ulcer (strength of recommendation: strong; quality of evidence: moderate).

2. Do not use any of the currently available classification/scoring systems to offer an individual prognosis for a person with diabetes and a foot ulcer (strong; low).

3. In a person with diabetes and an infected foot ulcer, use the IDSA/IWGDF infection classification to characterise and guide infection management (weak; moderate).

4. In a person with diabetes and a foot ulcer who is being managed in a setting where appropriate expertise in vascular intervention is available, use WIfI scoring to aid decision making in the assessment of perfusion and likelihood of benefit from revascularisation (weak; moderate).

5. Use the SINBAD system for any regional/national/international audits to allow comparisons between institutions on the outcomes of patients with diabetes and an ulcer of the foot (strong; high).

1 | INTRODUCTION

It is estimated that diabetes affects 422 million people worldwide, 8.5% of the adult population, and the increase in prevalence is occurring at a faster rate in low- and middle-income countries.[1] Around one in four people with diabetes will develop a diabetic foot ulcer (DFU) in their lifetime.[2] The risk of developing a DFU, and the factors associated with development of complications such as hospitalisation, lower extremity amputation (LEA), and mortality may be patient related, limb related or ulcer related. The impact of individual factors on the outcome of DFUs will vary across communities and across countries. For example, infection will more strongly influence outcome in countries where antibiotics are not readily available, whereas ischaemia will have a greater impact in countries where peripheral artery disease is more prevalent. Of note, 80% of people with diabetes live in low- and middle-income countries,[1] where many diagnostic tools are not easily available and are not expected to become so in the near future.

In our review,[3] we found a large number of proposed classification and scoring systems for DFUs, which suggests that none is ideal for routine use in populations worldwide. This perhaps also reflects the differing purpose of classification and scoring systems: for communication among health professionals (independent of the level of clinical care), for clinical prognostication and guidance of treatment, and for clinical audit of outcomes across units and populations. With this in mind, a classification system may be defined as a descriptive tool, dividing patients into groups but not necessarily relating this to risk of adverse outcome, whereas a scoring system will attribute a scale by which the contribution of factors within the system will be amalgamated to produce an overall (usually numerical) score with increased score being associated with higher risk of adverse outcomes.

The intended use of a classification or scoring system will influence its content. A system designed to assess risk or prognosis for a person with diabetes and an active ulcer on their foot will necessarily require more detailed information to provide a personalised outcome. By contrast, a system aiming to compare outcomes between populations, in which there is a need to minimise the requirement for additional data input by busy clinicians while including factors that influence outcome across differing populations, should have a less burdensome data collection and processing requirement if it is to be taken up by clinicians treating DFUs. Classifications used for communication between health professionals should ideally be simple to memorise and use. The aim of this guideline is to provide recommendations on the use of classifications of DFUs for various purposes.

2 | METHODS

This guideline has been compiled based on our review[3] and following consideration of recent review articles on DFU classification systems.[4-8] To identify factors associated with DFU outcome (healing, hospitalisation, amputation, and mortality), and to select the most pertinent, we searched for reports of large clinical cohorts.[9-15] A consensus was then reached, based upon expert opinion, of eight factors that were consistently and meaningfully related to DFU outcomes that would ideally constitute the basis of a classification system:

1. Patient factors: End stage renal disease
2. Limb factors: Peripheral artery disease; loss of protective sensation
3. Ulcer factors: Area; depth; location (forefoot/hindfoot); number (single/multiple); infection.

For determining the quality of evidence, we conducted a review[3] and assessed the presence and number of reliability (namely interobserver agreement) studies and internal and external validation studies for one or more clinical outcomes. Consistency and precision of the reported results were determined.

For providing the strength of recommendations, we analysed the quality of evidence, the complexity and components of the classification, the number of variables included that correspond to those eight factors selected by the group as being the most relevant, and if the classification corresponds to the purpose defined by its creators.

By consensus, we defined the following five clinical scenarios considered to be the most frequently encountered requiring classification of ulcers of the foot in patients with diabetes:

1. Communication among health professionals about the characteristics of a DFU
2. To assess an individual's prognosis with respect to the outcome of their DFU
3. To guide management in the specific clinical scenario of a patient with an infected DFU
4. To aid decision-making as to whether a patient with a DFU would benefit from revascularisation of the index limb
5. To support regional/national/international audit to allow comparison between institutions

For each clinical scenario, a clinical question was formulated having in consideration the PICO elements: population, intervention, comparator and outcome.

3 | RECOMMENDATIONS AND RATIONALE

PICO

In individuals with an active DFU, which classification system should be used in communication among health professionals to optimise referral?

Recommendation 1

In a person with diabetes and a foot ulcer, use the SINBAD system for communication among health professionals about the characteristics of the ulcer (strength of recommendation: strong; quality of evidence: moderate).

Rationale

For a classification system to be used by all health professionals managing people with a diabetic foot ulcer, it should be quick and simple to apply and requires no specialist equipment. For it to be useful to the receiving specialist, it should contain appropriate information to allow triage of patients to ensure timely review. Such a classification system should also be confirmed to have a high interobserver reliability.

Although all people with diabetes and an active DFU should be referred to a multidisciplinary diabetic foot team without delay, factors necessitating urgent review include the size of the ulcer (area and depth), presence of infection, and ischaemia. Any classification system for use as a triage tool will therefore need to include these criteria without the need for measurements requiring specialist equipment (eg, toe pressures, TcPO$_2$).

Classification systems that have been broadly externally validated for ulcer healing and LEA occurrence include Meggitt-Wagner, SINBAD, University of Texas, and WIfI.[3] Whilst simple to use, the Meggitt-Wagner classification does not allow for identification of PAD or infection, and whilst it has been validated for both healing and LEA,[16-23] there are also concerns regarding its consistency.[24] Thus, its use as a triage tool is limited. WIfI requires the use of specialist measurement of foot perfusion indices and although it therefore contains most of the key variables to allow for triage of people with a DFU, it is not ideal for use in primary/community care. The University of Texas system classifies DFUs using a bidimensional 4×4 matrix, according to depth (Grades 0, 1, 2, and 3) and presence of infection (Stage B), ischaemia (Stage C), or both (Stage D).[25] The original publication[25] described a combination of clinical signs and symptoms, plus one or more noninvasive criteria (transcutaneous oxygen measurements, ankle-brachial index, or toe systolic pressure) to assess perfusion and so is less useful

for communication among health professionals, as such equipment may not be available. In addition, loss of protective sensation and size (area) are not included in this classification.

The SINBAD system grades area, depth, sepsis, arteriopathy, and denervation plus site as either 0 or 1 point (see below), creating an easy to use scoring system that can achieve a maximum of 6 points,[26] as described in Table 1:

The SINBAD system is simple and quick to use, requiring no specialist equipment beyond clinical examination alone, and contains the necessary information to allow for triage by a specialist team. It would therefore be feasible to employ this classification system in localities where such equipment, including noninvasive measures of perfusion, are not readily available, which is the case for the majority of geographic settings where DFUs occur. If used for the purpose of communication between health professionals, it is important to use the individual clinical descriptors not merely the total score. This classification has been validated for both ulcer healing and amputation prediction,[12,13,16-20,22,26] presenting good results, and has good reliability.[24,27] Thus, the quality of the evidence was considered to be moderate.

PICO

In individuals with an active DFU, which classification/scoring system should be considered when assessing an individual patient to estimate their prognosis?

Recommendation 2

Do not use any of the currently available classification/scoring systems to offer an individual prognosis for a person with diabetes and a foot ulcer (strong; low).

TABLE 1 SINBAD system

Category	Definition	Score
Site	Forefoot	0
	Midfoot and hindfoot	1
Ischemia	Pedal blood flow intact: at least one palpable pulse	0
	Clinical evidence of reduced pedal flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial infection	None	0
	Present	1
Area	Ulcer <1 cm^2	0
	Ulcer ≥1 cm^2	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1
Total possible score		6

Rationale

We identified eight factors from large clinical DFU cohort studies associated with nonhealing, amputation and death: end-stage renal failure; peripheral artery disease; loss of protective sensation; area; depth; location (forefoot/hindfoot); single/multiple ulcers; and infection.[3] No existing classification system includes all eight of these factors.

To be used as a prognostic tool, a classification system needs to be complex enough to provide individualised outcome prediction yet quick to use within a busy clinical service, ideally not requiring measurements in addition to those performed for routine clinical care. The classification also needs to be validated for the population in which its use is proposed, as the dominant factors for poor outcomes in DFU vary worldwide. This validation should include how well the classification system predicts both ulcer healing and risk of amputation. The system should also have good interobserver and intraobserver reliability to provide consistent prognostic outcomes and allow for monitoring of progress with intervention. None of the systems met these criteria, and so further research may be required to either appropriately validate an existing classification or to develop a classification/scoring system according to these criteria.

Meggitt-Wagner, PEDIS, SINBAD, SEWSS, University of Texas, and WIfI have been externally validated for prediction of both ulcer healing and LEA within cohorts[3] but not at an individual level. Further, validation of WIfI has been largely performed in cohorts of patients with severe limb ischaemia across several continents, with one cohort specific to DFU and five additional papers including >75% patients with DFU.[28-32]

PEDIS was originally developed as a descriptive classification for use in research and not designed for prognostic purposes. It does not include patient factors (end-stage renal disease) or either the location or the number of foot ulcers. PEDIS has been validated in two studies for both wound healing and a composite endpoint of nonhealing, amputation, and death.[16,17] It has also been demonstrated to have good reliability.[27] Despite this, it is not a scoring system.

The Meggitt-Wagner classification is simple, but there are concerns regarding its consistency. It does not include reference to loss of protective sensation, infection, and ischaemia, and thus, its utility may vary between countries. It is also too simplistic to provide prognostic information at an individual level, including only two of the eight factors identified by the expert panel.

University of Texas is a descriptive classification, rather than a scoring system, containing only three of the eight prognostic factors identified by the expert panel. Good reliability has been reported.[24,27]

SINBAD and SEWSS are scoring systems designed to provide prognostic information. Both have been externally validated for prediction of wound healing and LEA occurrence on more than one continent,[12,19,20,26,33] and both have good reliability.[27,34] Both also contain six of the eight prognostic factors identified by the expert panel. The SEWSS classification is complex and time consuming to complete. Although studies have shown good reliability, in a comparison of 11 classifications scores for LEA, SEWSS had one of the lowest

areas under the curve on ROC analysis for discrimination between healing and nonhealing outcomes.[20]

The quality of evidence for the prediction of DFU outcomes is weak and not directly applicable to the accuracy of a classification system in predicting individual patient outcomes, leading to our strong recommendation against the use of any system for prediction of individual patient outcomes.

PICO

In persons with an active DFU, can any classifications/scoring system aid decision-making in specialty areas to improve healing and/or reducing amputation risk?

Recommendation 3

In a person with diabetes and an infected foot ulcer, use the IDSA/IWGDF infection classification to characterise and guide infection management (weak; moderate).

Recommendation 4

In a person with diabetes and a foot ulcer who is being managed in a setting where appropriate expertise in vascular intervention is available, use WIfI scoring to aid decision-making in the assessment of perfusion and likelihood of benefit from revascularisation (weak; moderate).

Rationale

Only two classification systems have been developed that provide stratification that aligns to clinical decision-making: IWGDF/IDSA and WIfI.[3] Of note, whilst the IWGDF/IDSA is incorporated into the WIfI, in situations where only infection is being assessed and equipment is not available to use WIfI, the IWGDF/IDSA infection classification can stand alone.

IWGDF/ISDA classification consists of four grades of severity for diabetic foot infection (see Table 2). It was originally developed as part of the PEDIS classification for research purposes and is used as a guideline for management, in particular to identify which patients required hospital admission for intravenous antibiotics. Although the components of each grade are complex, and a previous study has shown only moderate reliability, the criteria are widely used. Unsurprisingly, given the context of the IWGDF/IDSA classification, it is a strong predictor of the need for hospitalisation.[35] However it has also been validated for risk of both major and minor amputation.[20,24]

Both classifications have been validated on multiple occasions for various clinical outcomes with consistent results and presented adequate reliability values. So the quality of the evidence was considered to be strong. Due to their complexity and limited assessment in

TABLE 2 International Working Group on the Diabetic Foot/Infectious Diseases Society of America system

Clinical manifestations	Infection severity	PEDIS grade
Wound lacking purulence or any manifestations of inflammation	Uninfected	1
Presence of ≥2 manifestations of inflammation (purulence, erythema, tenderness, warmth, or induration), but any cellulitis/erythema extends ≤2 cm around the ulcer, and infection is limited to the skin or superficial subcutaneous tissues; no other local complications or systemic illness	Mild	2
Infection (as above) in a patient who is systemically well and metabolically stable but which has ≥1 of the following characteristics: cellulitis extending >2 cm, lymphangitic streaking, spread beneath the superficial fascia, deep-tissue abscess, gangrene, and involvement of muscle, tendon, joint, or bone	Moderate	3
Infection in a patient with systemic toxicity or metabolic instability (eg, fever, chills, tachycardia, hypotension, confusion, vomiting, leukocytosis, acidosis, severe hyperglycemia, or azotemia)	Severe	4

different populations and contexts, however, a weak strength of recommendation was given.

WIfI (see Table 3) uses a combination of scores for wound (based on depth of ulcer or extent of gangrene), ischaemia (based on ankle pressure, toe pressure or $TcPO_2$), and foot infection (based on IWGDF/IDSA criteria) to provide a 1-year risk for amputation and 1-year benefit for revascularisation, both stratified as very low, low, moderate, or high.[36] This has benefit over perfusion pressures alone by including associated wound and infection criteria to provide a more holistic wound overview in revascularisation decision-making. Whilst WIfI has not been subject to reproducibility assessment in a DFU cohort, it has impressive reproducibility in a PAD setting.[32] It has been validated in only one cohort exclusively of patients with an active DFU but has been shown in multiple validation studies to predict outcomes relevant to this clinical group such as healing, time to healing, need for revascularisation, LEA, LEA free survival, and mortality.[28-31] Both need for revascularisation and timing of revascularisation can be guided by the combination of risk estimate for amputation and benefit estimate for revascularisation.

PICO

In persons with an active DFU, which classification/scoring system should be considered for regional/national/international audit to allow comparisons between institutions?

Recommendation 5

Use the SINBAD system for any regional/national/international audits to allow comparisons between institutions on the outcomes of patients with diabetes and an ulcer of the foot (strong; high).

Rationale

In this document, the term "audit" refers to characterisation of all DFUs managed in a particular area or centre, in order to compare outcomes with a reference population or national standard, and does not allude to the financial implications of care. Ideally, one classification system should be used internationally to allow comparisons of outcomes. In order to do this, such a classification system would need to accurately assess DFU severity across the spectrum of aetiologies. Thus, health care systems where peripheral artery disease is a major contributor to nonhealing and LEA can be compared with health care systems where infection is a major cause of LEA because of limited antibiotic availability. Further, the system should be simple to use, and requires no specialist equipment, to allow the necessary clinical data to be collected routinely from all patients in all health care settings spanning the spectrum from low to high resource availability. Currently, SINBAD is the only classification system that meets all of these criteria. It has been validated for healing and LEA in diverse DFU populations[12,19,20,26,33] and has been shown to be acceptable to clinicians from use in the UK National Diabetes Foot Care audit of over 20 000 DFUs.[12] For these reasons, the quality of evidence was high, and strength of recommendation was considered strong.

4 | CONSIDERATIONS/FUTURE RESEARCH/KEY CONTROVERSIES

We were unable to recommend any of the currently available classification/scoring systems to provide an individual prognosis, which would guide management and could help the patient/family. Future research should be directed to develop and validate a simple reproducible classification system for the prognosis of the individual person with a DFU, their index limb or their ulcer.

None of the currently validated systems contained all eight of the important prognostic clinical features identified as part of the review process. Future research should be undertaken to establish whether increasing the complexity of classifications by the addition of features such as ESRD, single/multiple ulcers, more detailed site of ulcers (such as plantar/dorsum), or more detailed measures of limb ischaemia significantly improves the validity of the system to predict the outcome, without compromising reliability or clinical utility.

We consider that there may never be a single DFU classification system, since the specification of any classification will depend heavily on its purpose and clinical setting.

TABLE 3 Wound, Ischemia, and foot Infection system

Wound		
Grade	DFU	Gangrene
0	No ulcer	No gangrene
	Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.	
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
	Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.	
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
	Clinical description: major tissue loss salvageable with multiple (≥3) digital amputations or standard transmetatarsal amputation (TMA) ± skin coverage.	
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer ± calcaneal involvement	Extensive gangrene involving forefoot and/or midfoot; full thickness heel necrosis six calcaneal involvement
	Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or non-traditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect	

Ischemia			
Grade	Ankle-brachial index	Ankle systolic pressure (mmHg)	Toe Pressure, transcutaneous oxygen pressure (mmHg)
0	≥0.80	>100	≥60
1	0.6-0.79	70-100	40-59
2	0.4-0.59	50-70	30-39
3	≤0.39	<50	<30

Foot Infection	
Grade	Clinical manifestations
0	No symptoms or signs of infection Infection present, as defined by the presence of at least two of the following items: • Local swelling or induration • Erythema >0.5 to ≤2 cm around the ulcer • Local tenderness or pain • Local warmth • Purulent discharge (thick, opaque to white, or sanguineous secretion)
1	Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). Exclude other causes of an inflammatory response of the skin (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, and venous stasis)
2	Local infection (as described above) with erythema >2 cm, or involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, and fasciitis), and No systemic inflammatory response signs (as described below)
3	Local infection (as described above) with the signs of SIRS, as manifested by two or more of the following: • Temperature >38°C or <36°C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min or $PaCO_2$ <32 mmHg • White blood cell count >12 000 or <4000 cu/mm or 10% immature (band) forms

Abbreviations: DFU, diabetic foot ulcer; SIRS, systemic inflammatory response signs.

5 | CONCLUDING REMARKS

Classification of DFUs is of paramount importance in daily practice. It helps in communication between health professionals, assessment of prognosis and choice of best treatment strategy, and audit of clinical outcomes across units and populations.

The decision on which classification to use should rely on the included variables, available evidence around its validity and reliability, associated clinical outcomes and purpose. We encourage clinicians to use the classifications described in this guidance document. To do so, specific diagnostic tools are required and standardised definitions should be used.

CONFLICT OF INTEREST

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