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SUPPLEMENT ARTICLE

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Standards for the development and methodology of the 2019 International Working Group on the Diabetic Foot guidelines

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Abstract

Diabetic foot disease is a source of major patient suffering and societal costs. Investing in evidence-based international guidelines on diabetic foot disease is likely among the most cost-effective forms of health care expenditure, provided the guidelines are outcome focused, evidence based, and properly implemented.

The International Working Group on the Diabetic Foot (IWGDF) has published and updated international guidelines since 1999. The 2019 updates are based on formulating relevant clinical questions and outcomes, rigorous systematic reviews of the literature, and recommendations that are specific, and unambiguous along with their transparent rationale, all using the Grading of Recommendations Assessment Development and Evaluation (GRADE) framework.

We herein describe the development of the 2019 IWGDF guidelines on the prevention and management of diabetic foot disease, which consists of six chapters, each prepared by a separate working group of international experts. These documents provide guidelines related to diabetic foot disease on prevention; offloading; peripheral artery disease; infection; wound healing interventions; and classification of diabetic foot ulcers. Based on these six chapters, the IWGDF Editorial Board also produced a set of practical guidelines. Each guideline underwent extensive review by the members of the IWGDF Editorial Board as well as independent international experts in each field.

We believe that adoption and implementation of the 2019 IWGDF guidelines by health care providers, public health agencies, and policymakers will result in improved prevention and management of diabetic foot disease and a subsequent worldwide reduction in the patient and societal burden this disease causes.

KEYWORDS

diabetic foot, diabetic foot disease, foot ulcer, guidance, guidelines, implementation, IWGDF

1 | INTRODUCTION

The global prevalence of diabetes mellitus was 425 million in 2017 and is estimated to rise to 629 million by 2045; 75% of these people live in low- or middle-income countries.[1] Diabetic foot disease is a source of major patient suffering and societal costs. The frequency and severity of foot problems in persons with diabetes vary by region, largely because of differences in socio-economic conditions and standards of foot care.[2] Foot ulcers are the most recognizable problem, with a yearly incidence of around 2% to 4% in higher income,[2] likely

[†]International Working Group on the Diabetic Foot (IWGDF); www.iwgdfguidelines.org

even higher in lower income countries, and an estimated lifetime prevalence of 19% to 34%.[3]

The most important factors underlying the development of foot ulcers are peripheral neuropathy, foot deformities related to motor neuropathy, minor foot trauma, and peripheral artery disease.[3] These conspire to put the patient at risk for skin ulceration, making the foot susceptible to infection—an urgent medical problem. Only two-thirds of diabetic foot ulcers will eventually heal,[4] and up to 28% may result in some form of lower extremity amputation.[5] Every year, more than 1 million people with diabetes lose at least a part of their leg because of diabetic foot disease. This translates into the estimate that every 20-30 seconds, a lower limb is lost to diabetes somewhere in the world.[6]

Diabetic foot disease not only represents a personal tragedy for the affected patient; it also affects that person's family and places a substantial financial burden on health care systems and society in general. In low-income countries, the cost of treating a complex diabetic foot ulcer can be equivalent to 5.7 years of annual income, potentially resulting in financial ruin for the patient and their family.[7] Investing in evidence-based, internationally appropriate guidelines on diabetic foot disease is likely among the most cost-effective forms of health care expenditure, provided it is outcome focused and properly implemented.[8,9]

2 | INTERNATIONAL WORKING GROUP ON THE DIABETIC FOOT

The International Working Group on the Diabetic Foot (IWGDF; www.iwgdfguidelines.org), founded in 1996, consists of multidisciplinary experts involved in the care of patients with diabetic foot disease. The IWGDF aims to prevent the adverse effects of diabetic foot disease by developing and regularly updating the international guidelines for use by all health care providers, public health agencies, and policymakers involved in diabetic foot care. Developing and updating guidelines are managed by the IWGDF guidelines working groups. In 1999, the IWGDF published its first version of "International Consensus on the Diabetic Foot" and "Practical Guidelines on the Management and the Prevention of the Diabetic Foot." This publication has been translated into 26 languages, and more than 100 000 copies have been distributed globally. As health care systems and prevalence of pathologies differ across regions in the world, the guidelines have to be adopted to local circumstances where applicable. These documents have since been updated five times.

3 | FROM CONSENSUS TO EVIDENCE-BASED GUIDELINES

While the core principles on which the IWGDF was founded remain constant, the methodology by which the IWGDF guidelines have been developed has evolved over the past couple of decades. The initial guidelines, and each subsequent update, were developed by a consensus process and written by a panel of experts in the field. Systematic reviews were introduced in 2007 and formed the backbone of the guidelines' recommendations. Utilizing a multistep review process, these guidelines were then revised by the IWGDF Editorial Board, followed by critical evaluation by global IWGDF representatives, culminating in an agreed upon text. Finally, the IWGDF recruited representatives from over 100 countries around the world to help implement the recommended practices. In 2015, a new milestone was introduced to the IWGDF guideline development with implementation of the GRADE framework to formulate recommendations for clinical practice, based on both the available evidence and expert opinion (see below).

4 | THE 2019 UPDATE

For the 2019 IWGDF guidelines, the IWGDF Editorial Board invited chair persons with whom they selected international experts to constitute six multidisciplinary working groups, each tasked with producing a guideline on one of the following topics:

1. Prevention of foot ulcers in at-risk people with diabetes
2. Offloading interventions to heal foot ulcers in persons with diabetes
3. Diagnosis, prognosis, and management of peripheral artery disease in patients with diabetic foot ulcers
4. Diagnosis and management of foot infections in persons with diabetes
5. Interventions to enhance healing of chronic ulcers of the foot in persons with diabetes
6. Classification of diabetic foot ulcers

The first five guideline chapters are updates of the 2015 guideline on the topic, while the guideline on classification of diabetic foot ulcers is new for 2019. All can be found in this special issue on the diabetic foot and at www.iwgdfguidelines.org. As in earlier versions, the IWGDF Editorial Board produced a document titled "Practical guidelines on the prevention and management of diabetic foot disease," based on these six guideline chapters, intended as a brief outline of the essential parts of prevention and management of diabetic foot disease. We advise clinicians and other health care professionals to read the full guideline chapter on each topic for the specific and detailed recommendations and the rationale underpinning them, as well as the associated systematic reviews for detailed discussion of the evidence. In addition, and new in 2019, this publication provides a more detailed description of the GRADE methodology followed and the development of recommendations along with the rationale supporting them.

Also new in 2019, each working group first formulated clinical questions and relevant outcomes to guide the systematic review of the available literature and the writing of recommendations. These clinical questions were reviewed by both an international panel of independent external experts and the six members of the IWGDF Editorial Board. Once the drafted guidelines with recommendations were produced, these were sent for review to external experts (please see

below for more detail). Finally, new in 2019 is the development of a "Definitions and Criteria" document for the most commonly used terms in diabetic foot disease to serve as a term of reference for our global consumers. The IWGDF Editorial Board members (the authors of this publication), a total of 49 working group members, and a total of 50 external experts from 40 countries and five continents were involved in the development of the 2019 IWGDF guidelines.

The six guidelines, the systematic reviews supporting them, the practical guidelines, this development and methodology document and the definitions and criteria document are all published as freely accessible articles online in this special issue on the diabetic foot, and at www.iwgdfguidelines.org. We recommend that health care providers, public health agencies, and policymakers use these guidelines as the basis for developing their own local (regional or national) guidelines.

5 | METHODOLOGY USED FOR THE 2019 IWGDF SYSTEMATIC REVIEWS AND GUIDELINES

This section describes the various steps and methods set up by the IWGDF Editorial Board for use by the designated multidisciplinary working groups to develop guidelines for the prevention and management of diabetic foot disease. The aims were to produce high-quality systematic reviews to help inform each guideline, promote consistency among the guidelines developed, and ensure high quality documents.

In the IWGDF guidelines, we have followed the GRADE methodology, which is structured around clinical questions in the PICO (Patient-Intervention-Comparison-Outcome) format, systematic searches and assessment of the available evidence, followed by developing recommendations and their rationale.[10,11] We will describe five key tasks in the development of guidelines: (a) formulation of the clinical questions, (b) selection of relevant outcome measures, (c) performing a systematic review of the available literature, (d) writing the recommendations for clinical practice, and (e) external review and feedback.

5.1 | Formulation of clinical questions

Each working group started the guideline writing process with formulating the key clinical questions they intended to address. This was to provide focus and structure to the setup of the evidence-based guidelines along the line of what a clinician or a patient would ask regarding the care provided in clinical practice to persons with diabetic foot disease. The questions generally involved diagnosis or treatment, and the members of the working group reached consensus on the clinical questions they planned to address.

These clinical questions take the format of the "PICO," an acronym that at least includes the population (P) at risk (who are you studying?), the intervention (I) planned (what will you be doing?), and the outcome (O) of interest (what are the consequences of the intervention?). The C is for comparator or control, and concerns the main alternative to the intervention considered, but this is not always required or available.

The clinical questions developed by each working group were reviewed by the IWGDF Editorial Board and by a panel of independent international external experts in the field to ensure global relevance. These experts (in total 6-13 per working group) were selected by the working groups, under guidance of the editorial board. Following this multistep revision, the clinical questions were finalized in June 2018.

5.2 | Selection of relevant outcome measures

Each working group devised specific outcome measures that formed the basis of selecting the relevant topic(s) for the systematic review. The evidence was to be reported for these specific outcomes. Given the lack of a validated core outcome set for diabetic foot disease, the set of outcomes defined by the IWGDF-EWMA (European Wound Management Association)[12] were used as a guide to define the outcomes selected.

Each outcome was classified regarding its role in decision making as "critically important"; "important, but not critical"; or "not important." Working groups were informed that critical outcomes, which have a larger effect on decision making and recommendations, were the most important to address.

5.3 | Performing a systematic review

Each working group undertook at least one systematic review of the medical literature that was designed to form the basis for the evidence-based guidelines. Each systematic review was prepared according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[13] (http://www.prisma-statement.org). Each working group used the AMSTAR tool to check that they were addressing the most important aspects in their systematic review (https://amstar.ca/Amstar_Checklist.php). Systematic reviews were prospectively registered in the PROSPERO database for systematic reviews (https://www.crd.york.ac.uk/prospero/).

The literature databases used for each systematic review were PubMed (via Medline) and either EMBASE (via Ovid SP), the Cochrane database, or both. Each working group devised a search string for each database. Individual working groups could consult a medical librarian to help in devising their search string. Study designs included in the systematic review were meta-analyses, systematic reviews, and randomized controlled trials (RCTs). Depending on the number of papers found with these higher-level study designs, working groups could also include lower level designs, for example, non-RCTs, case-control studies, cohort studies, (controlled) before-and-after studies, interrupted time series, prospective and retrospective noncontrolled studies, cross-sectional studies, and case series. Case reports were excluded from the systematic reviews.

5.3.1 | Trial registries

The working groups searched two trial registries for ongoing studies: The World Health Organization International Clinical Trials Registry Platform (WHO-ICTRP) (http://apps.who.int/trialsearch/default.aspx) and the ClinicalTrials.gov registry (https://clinicaltrials.gov). A sensitive search string derived from the original search string for the systematic review was used to search for relevant studies in these trial databases.

5.3.2 | Validation set

To ensure that the search string used for the systematic review was robust, working groups created a validation set of approximately 20 known key publications for each systematic review before performing the literature search. If each of the papers in the validation set was not identified in the literature search performed, the working group modified the search string.

5.3.3 | Date of search

The literature search for all systematic reviews was conducted in July 2018 (between the first and 15th of the month). If highly relevant studies for the systematic review and guideline appeared between the date of search and the start of writing the systematic review a second literature search was conducted September first, 2018 for any interval updates.

5.3.4 | Assessing retrieved publications from the search

Two members of each working group independently reviewed publications by title and abstract to assess their eligibility for inclusion in the analysis based on four criteria: population; study design; outcomes; and intervention. At their discretion, the working groups could calculate Cohen kappa values to test for agreement between the two reviewers. The two reviewers discussed any disagreement on which publications to include and reached consensus. The same two reviewers independently assessed selected full-paper copies of included publications on the same four criteria for final eligibility. Reference lists of included papers were not tracked.

To assess for possible publication bias or selective reporting of results, the working groups assessed studies identified by trial registries in the WHO and ClinicalTrial.gov databases. From relevant trials identified from these databases, related publications were searched for in the original literature search database, using the trial registration number of these relevant trials. If no publications were identified, the principal investigator of the trial was contacted and asked about the status of the trial and any possible results from the trial.

5.3.5 | Classifying study design and level of evidence

For each included publication, we used the Scottish Intercollegiate Grouping Network (SIGN) algorithm for classifying study design for questions of effectiveness (http://www.sign.ac.uk/assets/study_design.pdf). The same two reviewers that reviewed publications for eligibility independently assessed included publications with a controlled study design for methodological quality (ie, risk of bias), using scoring sheets developed by the Dutch Cochrane Centre (http://netherlands.cochrane.org/beoordelingsformulieren-en-andere-downloads).

The two reviewers discussed any disagreement regarding risk of bias and reached consensus. The SIGN grading system was used as an initial guide for assigning the level of evidence, with the exception of excluding levels 3 and 4 evidence from the SIGN grading system.

(http://www.sign.ac.uk/assets/sign_grading_system_1999_2012.pdf).[14] Additional observational study designs were also considered and are described below. Level 1 refers to randomized controlled trials, and level 2 refers to case control, cohort, controlled before-and-after designs, or interrupted time series. Risk of bias was scored for each study as ++ (very low risk of bias); + (low risk of bias); or – (high risk of bias).

Additionally, individual working groups had the discretion to assess all publications with a controlled study design for quality using the 21-item scoring system for reports of clinical studies developed by the IWGDF in collaboration with the EWMA.[12] The outcomes on the 21-item scoring list were added to the comment box in the evidence table for controlled studies.

To prevent any conflict of interest, reviewers who were one of the authors of any study assessed for inclusion did not participate in the assessment, data extraction, or discussion of publications of that study.

5.3.6 | Rating of the quality of evidence

The quality of the evidence (QoE) obtained through the systematic review was rated per PICO and for each outcome, even if there were multiple outcomes for a specific intervention. The quality of evidence was rated as high, moderate, or low. We discarded the category "very low" used by some.

The starting point in the QoE rating when level 1 studies (RCTs) were involved was "high," the starting point for observational controlled studies (level 2, that is, cohort, case control) for rating was "low." Working group members could then lower the QoE based on the presence of:

- Risk of bias (scored from the risk of bias assessment per paper)
- Inconsistency of results (ie, true differences in the underlying treatment effect may be likely when there are widely differing estimates of the treatment effect [ie, heterogeneity or variability in results] across studies)

- Publication bias (as could be obtained from the Clinical Trials search), where appropriate

For each of these three items that was scored as "present," the QoE rating was lowered by one. For example, QoE could be reduced from "high" to "moderate" when risk of bias of included studies was high.

The QoE could be raised based on the presence of a large effect size or evidence of a dose-response relationship (for observational studies only). For each of these two items that was scored as "present," the QoE rating was raised by one. For example, QoE was raised from "low" to "moderate" when the effect size was large.

Many of the older papers identified in the systematic reviews lacked data to calculate or assess for indirectness or imprecision, two other factors that can be used to determine the QoE. Ideally, these items help to fully assess the QoE, but unfortunately, we could not take them into account.

5.3.7 | Data extraction

Data were extracted from each included publication that had a controlled study design and were summarized in an evidence table. This table included patient and study characteristics, characteristics of the intervention and control conditions, and primary and secondary outcomes. One of the reviewers of the original team of two extracted the data, while the other reviewer checked the table for content and presentation. All members of the working group discussed the data in the evidence tables.

Each working group created a PRISMA flow diagram showing the process of selection of papers for the qualitative analysis and a risk of bias table presenting in detail the risk of bias per included publication.

5.3.8 | Conclusions and evidence statements

Finally, the working group drew conclusions for each clinical question formulated. These were based on the strength of the available evidence and formulated as evidence statements. All members of the working group participated in the discussion of these conclusions, reaching consensus on the content and formulation of the conclusions.

5.3.9 | Systematic review on diagnostic procedures

We obtained specific methods to the systematic review on diagnostic studies from Brownrigg et al,[15] and we asked all groups systematically reviewing studies and writing guidelines on diagnostic procedures to follow the methods used in this study.[15] Diagnostic tests were considered as any specific evaluation that sought to identify the presence of a particular clinical outcome. Studies included were those that evaluated an index diagnostic test against a reference diagnostic test. Working groups assessed methodological quality of included studies against parameters included in the QUADAS tool, a consensus quality assessment tool designed specifically for diagnostic accuracy studies.[16] Reviewers extracted data and entered them in a QUADAS data extraction form and obtained or calculated positive and negative likelihood ratios for each test in each study as performance measure.[17,18]

5.3.10 | Systematic review on prognosis

The methods used for the systematic review on prognostics in peripheral artery disease were the same as the ones used in the 2016 systematic review on this topic.[19] Studies included evaluated investigations of peripheral artery disease or reduced perfusion and their level of abnormality that would predict ulcer healing or major amputation. To assess methodological quality of included studies, we used the Quality In Prognosis Studies (QUIPS) tool, designed specifically for prognostic studies.[20,21] To assess risk of bias, we used the QUIPS Risk of Bias Assessment Instrument for Prognostic Factor Studies was used. The positive and negative likelihood ratios for each test were obtained or calculated as primary outcomes.

5.4 | Writing the guideline recommendations

To formulate recommendations for clinical practice, we combined the overall quality of evidence as rated in the systematic review with different factors described in previous sections that were considered to determine the strength of the recommendations. This makes the link between the scientific evidence and recommendations for daily clinical practice.[11]

5.4.1 | Grading the strength of a recommendation

In accordance with the GRADE framework, we scored the strength of the recommendation as either "strong" or "weak." The different factors considered to come to this score were the following: the QoE rating; the balance between desirable and undesirable effects (benefit and harms); patient values and preferences; feasibility, generalizability and acceptability of the diagnostic procedure or intervention; and resource utilization (costs). Added to these were other factors, such as expert opinion and clinical relevance described in previous publications by the GRADE working group.[10,11]

The working group carefully weighed all these factors to determine the strength of the recommendation, then wrote a rationale for each recommendation to explain the arguments as discussed within the working group on these different factors. The weighing was only to a limited extent a quantitative process that could only be done when literature evidence on harms (eg, complications), patient preferences, or costs were available. Where this was not available, working groups used a more qualitative and subjective approach based on

expert opinion. Working group members reached consensus regarding the strength of the recommendations.

5.5 | External review and feedback

The members of the IWGDF Editorial Board met in person on a number of occasions to thoroughly review each of the guideline chapters, which were then revised by the working groups based on this editorial review. The working groups then sent the guideline to the panel of independent international external experts for their critical review. The working group subsequently revised the document further based on these comments, after which, the IWGDF Editorial Board did a final review of the recommendations and the rationale provided.

5.6 | Future guidelines

Finally, for future purposes, we will consider to revise and refine the methodology for the IWGDF guideline development as new concepts/recommendations evolve in the fields of systematic review and clinical practice guideline development. We are aiming to publish updated guidelines in 2023.

6 | CONCLUDING REMARKS

With the worldwide diabetes epidemic, it is now more imperative than ever that appropriate action be taken to ensure access to quality care for all people with diabetes, regardless of their age, geographic location, and economic or social status. The IWGDF guidelines on the prevention and management of diabetic foot disease are the result of a rather unique process that over 20 years has become more and more founded in a strong evidence base, with procedures to guarantee consistency, transparency, and independency. The evidence base for how to help prevent and optimally manage diabetic foot disease is progressively growing, but it remains a challenge how to use this data to optimize outcomes in different health care systems, in countries with different resources and in different cultures. The IWGDF hopes to see an increase in global awareness of diabetic foot disease and aims to stimulate this process of transforming global guidelines to local guidelines, leading to improved foot care throughout the world. Notwithstanding the limited published evidence of improved outcomes associated with using these IWGDF guidelines,[22] we believe that implementation of the 2019 IWGDF guidelines' recommendations will result in improved prevention and management of foot problems in diabetes and a subsequent worldwide reduction in the patient, economic and societal burden caused by diabetic foot disease.

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CONFLICT OF INTEREST

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All individual conflict of interest statement of authors of this guideline can be found at: https://iwgdfguidelines.org/about-iwgdf-guidelines/biographies/

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