

CONSENSUS DOCUMENT

Consensus document on actions to prevent and to improve the management of diabetic foot in Spain[☆]



Documento de consenso sobre acciones de mejora en la prevención y manejo del pie diabético en España

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PALABRAS CLAVE

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Úlcera de pie;
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Introduction

Diabetic foot disease is a serious complication of diabetes mellitus (DM), affecting 3-4% of people with DM around the world.¹ The lifetime prevalence of suffering from a foot ulcer among people with DM is in the range 19-34%.²

Some 70% of diabetic foot ulcers (DFUs) remain open 20 weeks after treatment,³ and their prognosis is seriously affected by the presence of ischaemia or infection. Over 50% of patients with DFU have peripheral arterial disease,⁴ especially in middle- and high-income countries. Nearly 60% of DFUs become infected and this is the main cause of amputation.⁵

In Spain, the incidence rate of major amputations per 100,000 people/year was 0.48 between 2001 and 2015, although this figure varied significantly between the different autonomous regions.⁶ The five-year risk of death for a patient with a diabetic foot ulcer is two to five times greater than for a patient with no ulcer, and up to 70% of patients may die within five years after a major amputation.⁷ The hospital mortality rate associated with major amputation in Spain is 10%.⁶

Success in the prevention and treatment of diabetic foot disease depends on a well-organised multidisciplinary team using a holistic approach, in which the ulcer is seen as a sign of multi-organ disease. The effective organisation of this care requires systems and guidelines for education, detection, risk reduction, treatment and auditing. Comprehensive patient care, which includes follow-up and continuity of care, both in primary care and in specialised diabetic foot units, is key in the effective management of these patients.⁸

Development of the consensus statement

New guidelines on the management and prevention of diabetic foot, put together by the International Working Group on the Diabetic Foot (IWGDF), were launched in The Hague in May 2019.⁸ The organisation responsible for the implementation of the guidelines at an international level is D-FOOT International, which aims, through various projects such as AB(b)A (Auditing, Benchmarking and Accreditation: in Search of Excellence), to carry out specific actions in different countries to facilitate implementation of the IWGDF guideline recommendations.

In October 2019, representatives of the working groups on diabetic foot from the Sociedad Española de Diabetes (SED) [Spanish Diabetes Association] and the Sociedad Española de Angiología y Cirugía Vascular (SEACV) [Spanish Society of Angiology and Vascular Surgery] met in Santiago de Compostela with members of the Administración del Servicio Gallego de Salud (SERGAS) [Galician Health Service], representatives of diabetes patients, through the Federación Española de Diabetes (FEDE) [Spanish Diabetes Federation], and representatives of the pharmaceutical industry. At that meeting, they committed to designing actions based on the IWGDF guideline recommendations to improve the management of diabetic foot. Consensus was to be reached by minimum agreement on actions which could be adopted and implemented by any healthcare professional involved in the care of patients with diabetic foot, regardless of their experience in the management of these patients or the care level they worked in (from primary to specialised care).

A group of experts made up of representatives from the SED, the SEACV, primary care nursing and specialised care nursing, and under the umbrella of D-FOOT International, met in Madrid on 30 January 2020 to design actions for improving the basic concepts of care for patients with diabetic foot. The group was formed by healthcare professionals in nursing, podiatry and medicine from the specialist areas of endocrinology, angiology and vascular surgery.

The experts were distributed across four groups, ensuring multidisciplinary representation in each group, and they analysed the recommendations included in the 2019 IWGDF guidelines on the prevention and risk stratification of diabetic foot ulcer, the diagnosis and management of peripheral arterial disease, infection control and local wound healing.

The different chapters of the guidelines were reviewed and the recommendations and action plan were agreed upon for each scenario, with the principle of universality, feasibility and applicability to the Spanish National Health Service. Each group drew up a series of recommendations and improvement actions, which were then discussed in open forum with the other groups, with a final consensus being reached at the end of the meeting by all members. Finally, a document was drawn up with all the recommendations and was circulated by email three times until final consensus was reached by each and every one of the members of the working group.

Chapter 1. Risk classification and preventive actions⁸

The primary care team (doctor and nurse) will be responsible for performing vascular and neuropathic screening in order to assess the degree of risk of developing a diabetic foot ulcer.

If the patient is being treated by other specialists, the endocrinologist, nursing home doctor and/or internal medicine physician must ensure that these interventions are carried out.

- Take a thorough medical history in order to analyse cardiovascular risk, chronic complications of diabetes and other comorbidities the patient may have.

Table 1 Categorisation of the risk of diabetic foot ulcer. Adapted from the IWGDF 2019 guidelines.⁸

Category	Ulcer risk	Characteristics	Frequency+
0*	Very low	No neuropathy, no PAD, no foot deformity	Once a year
1*	Low	Neuropathy or PAD or foot deformity	Once every 6 to 12 months
2	Moderate	Neuropathy + PAD <i>or</i> neuropathy + foot deformity <i>or</i> PAD + foot deformity	Once every 3 to 6 months
3	High	Neuropathy or PAD, and one or more of the following: - History of foot ulcer - Lower limb amputation (minor or major) - End-stage kidney disease	Once every 1 to 3 months

+ Follow-up frequency should be based on the judgement of the healthcare professional responsible for the patient, as the evidence to support these intervals is insufficient.

* Modification of grades 0 and 1, based on the IWGDF classification.

- Perform vascular screening in all patients with diabetes. This must be non-instrumented, by palpation of distal foot pulses (posterior tibial and pedal), and assessment of vascular signs and symptoms, presence of ulceration, pain at rest and/or intermittent claudication.
- Perform neuropathic screening using the Semmes-Weinstein monofilament test, examining three points at the plantar surface located on the ball of the big toe and under the first and fifth metatarsal heads, exerting perpendicular pressure on the area to be examined. If any one of them cannot be felt, nerve damage is confirmed.
- Assess the presence of deformities in the feet of diabetes patients, based on the presence of deformities, calluses and/or the pattern of hyperkeratosis, giving particular attention to the toes and the plantar area of the forefoot.
- Ensure suitable referral, according to the patient's level of risk and the complication detected.
 - Consider referral to a multidisciplinary diabetic foot unit for assessment of the need for corrective orthopaedic surgery if the patient has deformities which may increase the risk of ulceration, before the development of diabetes-related complications, and particularly peripheral arterial disease (PAD). If there is no such unit, refer the patient to an orthopaedic surgeon.
 - In cases with absence of distal pulses but presence of ulceration, pain at rest, and/or intermittent and/or disabling claudication, the patient should be referred to the angiology and vascular surgery specialist for assessment of other interventions.
- Guarantee access to a podiatrist for basic foot care, according to the patient's risk, offloading based on the biomechanical alteration within the degree of risk of developing ulceration, and the prescription of therapeutic footwear.
- Classify the risk of ulceration and the frequency of therapeutic interventions according to the characteristics of the patient (see Table 1).
- In addition to the treatment for diabetes, including diet and physical activity, the patient should receive recommendations and health advice directed at controlling metabolic status and risk factors (lipids, hypertension, smoking, weight control, anti-platelet therapy, etc.).
- Promote patient education as regards clothing (socks), footwear, and foot and toenail care and hygiene.
- Make patients aware of the potential risk of sudden changes in their daily activity (unexpected walks, sight-seeing trips, shopping days, etc.), and warn them of the risk in terms of injuries, grazes or blisters.

Chapter 2. Diagnosis, referral and management of peripheral arterial disease (PAD)⁹

- Examine distal pulses (posterior tibial and pedal) to rule out PAD in all diabetic patients with ulcers. If no pulses are found, they should be referred to a specialised angiology and vascular surgery unit/service.
- In diabetic patients with an ulcer, in addition to ischaemia, assess the characteristics of the ulcer and the degree of infection (WIFI [Wound, Ischemia and foot Infection] Classification) in order to stratify the risk of amputation and the benefits of revascularisation.
- Revascularisation should be considered, regardless of the results of routine tests, if an ulcer does not show signs of healing after four to six weeks of appropriate management.
- Any centre treating patients with diabetic foot ulcers should have experience in revascularisation techniques, both open and endovascular.
- A multidisciplinary team should guarantee the follow-up and management of the patient after the revascularisation procedure, both of the patient in general and of the standard of the ulcer treatment.
- If a diabetes patient with an ulcer has both ischaemia and infection, they should be assessed urgently, as they are at particularly high risk of limb loss and mortality.
- Ensure integral management of all risk factors in patients with diabetes and PAD, according to the aims of secondary cardiovascular prevention.

Chapter 3. Diagnosis, referral and management of infection⁵

- Assess the severity of any diabetic foot infection using the Infectious Diseases Society of America

(IDSA)/International Working Group on the Diabetic Foot (IWGDF) and SEACV classification systems.

- Rule out osteomyelitis associated with diabetic foot ulcer using the probe-to-bone test and, if possible, plain X-ray.
- Consider requesting an advanced imaging study (particularly magnetic resonance imaging) if the diagnosis of osteomyelitis remains uncertain.
- Consider microbiological culture of bone tissue in the event of clinical and/or morphological suspicion of osteomyelitis, and especially when starting long-term antibiotic therapy.
- Obtain a sample of the ulcer for culture aseptically by curettage, biopsy or aspiration, and not using any type of swab, when soft-tissue infection is suspected.
- Select an empirical antibiotic to treat a diabetic foot infection, based on the aforementioned clinical guidelines (IDSA/IWGDF/SEACV), adjusting therapy according to the microbiological culture results.
- Do not use topical antimicrobial therapies for specific treatment of the infection.
- Consult a surgical specialist urgently (within 24 hours) if the infection is being treated by a non-surgical specialist and is moderate or severe, with or without osteomyelitis, so they can perform urgent, energetic and definitive debridement.
- Guarantee the follow-up and management of the patient by a multidisciplinary team, to ensure secondary prevention treatment and avoid relapses or further ulcerations.

Chapter 4. Approach for patients with diabetic foot ulcer¹⁰

Considerations prior to managing patients with lesions:

If your centre/unit is going to treat diabetic foot lesions, the following will be necessary:

- Identify your referral unit for appropriate referral of patients with complicated lesions.
- Have staff suitably trained in specific skills:
- Vascular examination: palpation of distal pulses of the foot (posterior tibial and pedal).
- Assessment of infection.
- Examination of ulcer/assessment of bone exposure: probe-to-bone test.
- Surgical debridement.
- Application of basic lesion offloading systems.
- Consider carrying out training/awareness campaigns for diabetes patients about their illness.

Approach for the ulcer:

- Before taking any action on the lesion, you should:
- Rule out the presence of ischaemia: palpation of pulses.
- Rule out the presence of infection: assessment of clinical signs.
- Erythema/redness.
- Suppuration.
- Pain on plantar palpation.
- Crackling.
- Examine and stratify the lesion:
- Presence of necrosis.

- Exposure of deep planes (bone or tendon): probe-to-bone test.
- Stratify all ulcers being treated and monitor their progression over two weeks in order to assess whether or not it is necessary to refer the patient on.
- Include the following aspects in the ulcer treatment strategy:
- Foot hygiene: washing with pH neutral soap and normal saline solution.
- The lesion should be surgically debrided frequently, according to how it evolves.
- The patient's usual footwear should be removed and replaced with a basic offloading device, such as post-surgical footwear.
- Relative rest is recommended for the patient, avoiding the development of dependent oedema.
- Local ulcer care should be based on:
- Use of materials which allow wound care to be spaced to at least 48-72 h (for uncomplicated ulcers). Wound care should be adapted at the discretion of the healthcare professional responsible for the patient's continuing care (for complicated ulcers with ischaemia or infection).
- Adequate management of exudate, which includes the choice of dressings, and control of oedema.
- Consider using sucrose octasulfate dressings as the first treatment option in neuroischaemic ulcers or those not responding to standard treatment.
- The entire foot should be isolated using a non-compressive support bandage.
- Ensure that patients with diabetic foot ulcers are assessed medically:
- Perform lab tests which include blood count as well as blood glucose, lipid and nutritional profile.
- Assess the need for protein supplements and correction of anaemia or iron deficiency.
- Analyse vascular risk factors and optimise secondary prophylaxis measures:
- Maintain HbA1c below 8%, avoiding episodes of hypoglycaemia.
- Maintain systolic blood pressure in line with international guideline target levels.
- Maintain cholesterol levels within the international recommendation ranges. Prescribe statins when indicated.
- Avoid smoking.

Recommendations on "What not to do":

- Use pulse palpation as the first screening test and not the ankle brachial index (ABI) in patients with diabetes and foot ulcers.
- Do not take cultures of the ulcer if there is no infection.
- Do not use antibiotics for prophylactic purposes or to promote healing.
- Do not use foot soaks on diabetes patients.
- The patient should not wear their usual footwear when they have an active ulcer.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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