Guidelines for the prevention of diabetic ulcers

David L. Steed, MD1,2; Christopher Attinger, MD3; Harold Brem, MD4; Theodore Coiazzini, CPed, COE5; Mary Crossland, RN6; Michael Franz, MD7; Lawrence Harkless, DPM8; Andrew Johnson, BS9; Hans Moosa, MD10; Martin Robson, MD11; Thomas Serena, MD12; Peter Sheehan, MD13; Aristidis Veves, MD14; Laurel Wiersma-Bryant, RN, BC, ANP15

1. Chaired this panel,
2. University of Pittsburgh/UPMC, Pittsburgh, Pennsylvania,
3. Georgetown University Hospital, Washington, DC,
4. Columbia University College of Physicians and Surgeons, Department of Surgery, New York, New York,
5. Colazzi Pedorthic Center, Pittsburgh, Pennsylvania,
6. HCA Richmond Retreat Hospital, Richmond, Virginia,
7. University of Michigan Hospital, Ann Arbor, Michigan,
8. University of Texas Health Science Center, San Antonio, Texas,
9. Covance, Princeton, New Jersey,
10. St. Joseph’s Hospital, Belleville, Illinois,
11. University of South Florida, Tampa, Florida,
12. Penn North Centers for Advanced Wound Care, Warren, Pennsylvania,
13. Cabrini Medical Center, New York, New York,
14. Beth Israel Deaconess Medical Center, Boston, Massachusetts, and
15. Barnes-Jewish Hospital at Washington University Medical Center, St. Louis, Missouri

The Wound Healing Society (WHS) is a professional society of physicians, nurses, physical therapists, podiatrists, and other wound care specialists, basic scientists, clinical researchers, and industrial researchers dedicated to assuring that every patient receives optimal wound care. Its mission is to advance the science and practice of wound healing. To that end, the following comprehensive, evidence- and consensus-based guidelines were developed to address The Prevention of Diabetic Ulcers. The guidelines are presented in generic terms; the details of specific tests, therapies, and procedures are at the discretion of an interdisciplinary team of health care professionals who establish, implement, and evaluate policies and procedures directed at prevention of diabetic ulcers.

METHODS

PubMed, EMBASE, CINAHL, and the Cochrane Database of Systematic Reviews were searched and reviewed for evidence on arterial insufficiency ulcer prevention. In addition, a search of health care databases for current evidence-based guidelines addressing the prevention of diabetic ulcers was conducted using electronic and online resources. The panel classified studies based on whether the intervention being evaluated addressed diabetic ulcer risk screening and assessment, diabetic ulcer prevention plans of care (including interdisciplinary approaches), or patient and caregiver education.

Evidence references for each standard are listed and coded. The code abbreviations for the evidence citations were as follows:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAT</td>
<td>Statistical analysis, meta-analysis, consensus statement by commissioned panel of experts</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized clinical trial</td>
</tr>
<tr>
<td>LIT REV</td>
<td>Literature review</td>
</tr>
<tr>
<td>CLIN S</td>
<td>Clinical case series</td>
</tr>
</tbody>
</table>

Classification of evidence

The strength of evidence supporting a guideline is listed as Level I, Level II, or Level III, using the following definitions:

- **Level I**: Meta-analysis of multiple RCTs or at least two RCTs supporting the intervention in the guideline or multiple laboratory or animal experiments with at least two clinical series supporting the laboratory results.
- **Level II**: Less evidence than Level I, but at least one RCT and at least two significant clinical series or expert opinion papers with literature reviews supporting the intervention. Experimental evidence that is quite convincing but without support by adequate human experience.
- **Level III**: Suggestive data of proof-of-principle, but lacking sufficient data such as meta-analysis, RCT or multiple clinical series.

REFERENCES


GUIDELINES

Preamble: Patients with diabetes develop wounds as a result of neuropathy, peripheral vascular disease with ischemia, or both. In 2002, there were 19.3 million people with diabetes mellitus, for a crude incidence of 9.3%. The diagnosis of diabetes had been established in 6.5%, with 2.8% undiagnosed. There are now an estimated 20.8 million people in the United States with diabetes. As many as 25% of these patients are at risk for ulceration during their lifetimes. Preventing wounds may reduce the likelihood of amputation. Establishing the proper diagnosis is imperative, as is evaluation of the patient for the complications of diabetes. Prevention of wounds in these patients involves addressing these complications before ulceration.

1. Identifying Complications of Diabetes Leading to Ulceration:

Guideline #1.1: In patients with diabetes, clinically significant arterial disease should be ruled out by establishing that pedal pulses are clearly palpable or that the ankle:brachial index (ABI) is > 0.9. An ABI > 1.3 suggests noncompressible arteries. In elderly patients or patients with an ABI > 1.2, a normal Doppler derived wave form, a toe:brachial index of > 0.7 or a transcutaneous oxygen pressure of > 40 mmHg may help to suggest an adequate arterial flow. Color duplex ultrasound scanning provides anatomic and physiologic data confirming atherosclerotic occlusive disease.

Level of Evidence: I.

Principle: Diabetic ulcers can result from minor trauma in patients with arterial insufficiency. Although clinical history and physical examination can be suggestive of ischemia of the lower extremity in a patient with diabetes, a definitive diagnosis must be established.

Evidence:


Guideline #1.2: The presence of significant neuropathy that can render a patient at risk of foot ulceration can be determined by testing with a 10g (5.07) Semmes–Weinstein monofilament. Monofilament testing should be combined with a clinical examination of the lower extremity that focuses on the possible existence of foot deformity and a symmetric sensory level below which there is reduced sensation to pain, touch and vibration in both limbs.

Level of Evidence: II.

Principle: The most important causative factor of diabetic foot ulcers is peripheral neuropathy. Neuropathy leads to foot deformity with abnormal pressure on the foot, especially the plantar surface. Lack of protective sensation allows ulceration in areas of high pressure. Autonomic neuropathy may increase the likelihood of skin breakdown.

Evidence:


3. Foltz K, Fallat L, Schwartz S. Usefulness of a brief assessment battery for early detection of Charcot foot

Guideline #1.3: In patients with diabetes, laboratory values such as hemoglobin A1c should be monitored.

Level of Evidence: II.

Principle: High glucose concentrations in the blood lead to increased glycation of the hemoglobin molecules to form hemoglobin A1C, which persists in circulation for up to 6 weeks. Therefore, measurement of plasma hemoglobin A1C is the accepted standard for monitoring long-term glucose control. Elevated hemoglobin A1C levels have been correlated with a variety of comorbidities of diabetes, such as cardiovascular and/or coronary heart disease, retinopathy, neuropathy, and nephropathy/renal failure. Elevated hemoglobin A1C has been shown to be a predictive factor in the development of diabetic foot ulcers but further research is still required.

Evidence:

2. Perform Foot Exam for Clinical Manifestations of Diabetes that Increase Risk of Ulceration:

Guideline #2.1: Patients with diabetes should have an annual foot exam.

Level of Evidence: I.

Principle: Published guidelines uniformly recommend that all diabetic patients have an annual foot examination that includes assessment for anatomic deformities, skin breaks, nail disorders, loss of protective sensation, diminished arterial supply, and improper footwear. People with higher risk for foot ulceration should have more frequent foot exams.

Evidence:


Guideline #2.2: Patients with diabetes should be examined for callus formation.

Level of Evidence: III.

Principle: Callus formation, particularly with hemorrhage, is a sign of impending skin breakdown and ulceration. Removal of the callus results in lowered plantar pressures.

Evidence:

Guideline #2.3: Patients with diabetes should be examined for fungal toenails.

Level of Evidence: III.

Principle: Onychomycosis, a fungal infection of the nails, affects approximately one-third of patients with diabetes and is the source of extensive morbidity. Fungal toenails often harbor bacteria that can cause infection after injury to the skin, often initiated by the sharp and brittle nails themselves. Treatment options include oral antifungal agents, topical therapy, and mechanical intervention.

Evidence:


3. Surgery to Prevent Ulceration:

Guideline #3.1: Increased pressure on areas of the diabetic foot results in callus formation, which can then lead to ulceration. Removal of callus will reduce the likelihood of ulceration.

Level of Evidence: I.

Principle: Paring callus will reduce pressure in areas at increased risk for ulceration; therefore, all calluses should be removed with few exceptions.

Evidence:

Guideline #3.2: Achilles tendon lengthening decreases forefoot plantar pressure. This procedure may be recommended only for patients with history of repeated foot ulceration in whom all other non-interventional care has failed.

Level of Evidence: II.

Principle: Decreasing elevated forefoot plantar pressure is associated with a decrease in risk of ulceration.

Evidence:


4. Protect the Diabetic Foot:

Guideline #4.1: Protective footwear should be prescribed in any patient at risk for ulceration (significant arterial insufficiency, significant neuropathy, or previous amputation).

Level of Evidence: II.

Principle: Diabetic ulceration may result from an increase in pressure in the diabetic foot because of foot deformity and neuropathy. Offloading reduces the area of high pressure. The incidence of ulceration in diabetic patients at risk can be reduced by using protective footwear. Protective footwear should be prescribed in any patient at risk for amputation (such as significant arterial insufficiency, significant neuropathy, previous amputation, previous ulceration, pre-ulcerative callus, foot deformity, or evidence of callus formation).

Evidence:


Guideline #4.2: Patients with healed diabetic ulcers should use protective footwear to prevent recurrence.

Level of Evidence: II.

Principle: Diabetic ulcers of the lower extremity are a chronic problem. Recurrence rates are 8–59%. Therefore, long-term maintenance must be addressed even for healed ulcers. Most treatments do not eliminate the underlying increased pressure on the foot, so offloading is necessary long term.

Evidence:


5. Good Foot Care:

**Guideline #5.1:** Good foot care and daily inspection of the feet will reduce the incidence of diabetic ulceration. It may be necessary for a family member or caregiver to help with these tasks.

**Level of Evidence:** II.

**Principle:** Good foot care, including proper bathing and nail trimming, and the use of proper footwear, will reduce ulceration in diabetic feet.

**Evidence:**


6. Education:

**Guideline #6.1:** Education of patients with diabetes, aimed at preventing foot wounds, may reduce the incidence of ulceration and amputation, especially in high-risk patients.

**Level of Evidence:** II.

**Principle:** Education of patients, using a diabetes educator if available, may help them to practice good foot care behavior.

**Evidence:**


**Guideline #6.2:** Education of clinicians about patients with elevated risk for lower extremity amputation may reduce the risk of ulceration.

**Level of Evidence:** III.

**Principle:** Clinicians who are aware of patients with increased risk of foot ulceration are more likely to prescribe preventive foot care behaviors.

**Evidence:**