

JAMA Clinical Guidelines Synopsis

Management of a Diabetic Foot

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GUIDELINE TITLE Management of a Diabetic Foot**DEVELOPER** Society for Vascular Surgery (SVS), American Podiatric Medical Association, Society for Vascular Medicine**RELEASE DATE** February 2016**FUNDING SOURCE** SVS**TARGET POPULATION** All patients with diabetes**MAJOR RECOMMENDATIONS AND RATINGS** (1) Annual foot inspections by physicians or advanced practice clinicians with training in foot care and education of patients and their families

about preventive foot care are recommended for patients with diabetes (grade 1C). (2) Foot examinations in patients with diabetes should include testing for peripheral neuropathy using the Semmes-Weinstein test (grade 1B). (3) Annual assessment is recommended of pedal perfusion by ankle-brachial index (ABI), ankle and pedal Doppler arterial waveforms, and either toe systolic pressure or transcutaneous oxygen pressure (TcPO₂) for patients with a current diabetic foot ulcer (DFU) (grade 1B). (4) Adequate glycemic control (hemoglobin A_{1c} <7%) should be achieved to reduce DFUs and infections with subsequent risk of amputation (grade 2B). (5) Revascularization by surgical bypass or endovascular therapy is recommended for patients with DFU and peripheral arterial disease (PAD) (grade 1B). (6) Prophylactic arterial revascularization to prevent DFUs should not be done (grade 1C).

Summary of the Clinical Problem

Diabetes affects more than 29 million people in the United States and 415 million people worldwide.¹ The prevalence is increasing and expected to exceed 640 million people in 2040.¹ Presently, as many as 1 in 4 patients with diabetes develops a DFU, of which at least one-quarter do not heal, putting patients at risk of amputation.² The guideline focuses on interventions that decrease the burden and costs of all stages of diabetic foot syndrome; this synopsis specifically reviews the preventative measures considered.

Characteristics of the Guideline Source

Guideline development was sponsored by the SVS in collaboration with the American Podiatric Medical Association and Society for Vascular Medicine and used the GRADE framework. These organizations selected a multidisciplinary committee of vascular surgeons, podiatrists, and physicians with expertise in vascular and internal medicine to form the Diabetic Foot Practice Guidelines Committee. A guideline methodologist, a librarian, and a team of investigators with experience in conducting systematic review and meta-analysis assisted the committee. Five full systematic reviews and meta-analyses were published concomitant to the guideline. The committee used the evidence as well as unanimous expert consensus to formulate its recommendations. The final guidelines were peer reviewed by the SVS documents oversight committee. All committee members completed conflict of interest disclosures and more than 50% of the writing group was free of relevant conflicts; the chair overseeing the guideline development had no relevant conflicts³ (Table).

Evidence Base

Several small prospective studies support recommendations for annual foot examinations and education of patients and family mem-

bers. One trial randomized 145 patients with diabetes and history of foot ulcer to multidisciplinary care by foot specialists with access to footwear and education as well as quarterly primary care follow-up vs quarterly primary care follow-up and education alone.⁴ The rate of recurrent ulcer in the intervention group was 30.4% at 2 years vs 58.4% in the control group (odds ratio [OR], 0.31; 95% CI, 0.14-0.67).⁴

Use of the Semmes-Weinstein test is supported by numerous studies.⁵ In a review of 6 prospective studies and 10 observational studies, positive test results were associated with ORs between 2.2 and 9.9 for the development of ulcers at 1- or 2-year follow-up.⁶

A meta-analysis was performed to assess the accuracy of tests to predict wound healing. Observational data were available for studies that assessed ABI (20 studies; 2376 patients) and TcPO₂ (25 studies; 3789 patients).⁷ An ABI threshold of less than 0.8 was predictive of amputation (OR, 2.89; 95% CI, 1.65-5.05) but not complete ulcer healing (OR, 1.02; 95% CI, 0.40-1.65).⁷

Table. Guideline Rating

Standard	Rating
Establishing transparency	Good
Management of conflict of interest in the guideline development group	Good
Guideline development group composition	Fair
Clinical practice guideline-systematic review intersection	Good
Establishing evidence foundations and rating strength for each of the guideline recommendations	Good
Articulation of recommendations	Good
External review	Fair
Updating	Fair
Implementation issues	Good

A TcPO₂ threshold of less than 30 mm Hg was predictive of complete ulcer healing (OR, 15.81; 95% CI, 3.36-74.45) and risk of amputation (OR, 4.14; 95% CI, 2.98-5.76). Six additional non-invasive tests reviewed did not have sufficient patient numbers to perform appropriate meta-analysis.⁷

To examine the large body of evidence that exists comparing intensive and less intensive glycemic control strategies and their effect on preventing diabetic foot syndrome, the authors analyzed 9 randomized trials enrolling 10 897 patients with diabetes without DFUs.⁸ In these studies, intensive glucose control (hemoglobin A_{1c} 6%-7.5%) was associated with a significant decrease in risk of amputation (relative risk [RR], 0.65; 95% CI, 0.45-0.94) and slower decline in the sensory vibration threshold (mean difference, -8.27 μm; 95% CI, -9.75 μm to -6.79 μm) but not with ischemic changes (development of gangrene, ischemic ulcer, new-onset claudication, or new diagnosis of PAD) (RR, 0.92; 95% CI, 0.67-1.26) or new-onset peripheral or autonomic neuropathy on annual examination (RR, 0.89; 95% CI, 0.75-1.05).⁸

A previously commissioned systematic review including 49 non-randomized studies and 8290 patients was used to analyze the effectiveness of revascularization in the setting of PAD and a DFU.⁹ Open revascularization had a median 2-year limb salvage rate of 85% (interquartile range, 80%-90%); the rate for endovascular intervention was 78% (interquartile range, 70.5%-85.5%).⁹ In 7 studies reporting wound healing, more than 60% of ulcers healed following revascularization at 1 year.⁹

There is insufficient trial evidence demonstrating any improvement in DFU after prophylactic revascularization. The higher prevalence of long-segment and distal occlusive disease in patients with diabetes, endothelial damage induced by interventions, and significant perioperative complication risks associated with both endovascular and open revascularization are compelling reasons to pursue nonoperative approaches to prevention.³

Benefits and Harms

The benefits of improving diabetic foot care are decreased rates of DFUs and their associated sequelae of infection and amputation, out-

comes associated with improved physical and emotional functioning for patients, improved productivity, and decreased total health care costs.³ Preventive care and noninvasive testing have no associated harms intrinsic to the tests. False-positive test results do occur (there is a high prevalence of medial calcinosis in patients with diabetes that may falsely elevate the ABI), and these are associated with increased costs.³

Discussion

The prevalence of PAD among patients with diabetes is between 10% and 40%, and the incidence is increasing worldwide.³ Concomitantly, an increasing proportion of DFUs have an ischemic component. Ischemic ulcers are associated with higher recurrence rates, higher amputation rates, and decreased levels of functional independence compared with neuropathic ulcers.³ The guidelines direct special attention to this trend by recommending regular assessment for PAD as a component of preventative diabetic foot care in conjunction with optimal glycemic control. Comprehensive multidisciplinary foot care at all stages of diabetic foot syndrome is essential to improve patient care and ultimately to reduce the substantial burden of this challenging disease.

Areas in Need of Future Study or Ongoing Research

The systematic reviews associated with this guideline indicated a need for comparative effectiveness research examining the tests that predict wound healing as well as the methods of debridement. Similarly, several of the systematic reviews revealed a paucity of evidence regarding effective interventions beyond hyperbaric oxygen therapy or off-loading methods with therapeutic shoes and insoles.

Randomized trials comparing endovascular and open revascularization in patients with diabetes across a spectrum of clinical presentation are needed. The guideline acknowledges that both techniques currently have roles in limb salvage, but there are limited data regarding which patients may benefit more from a given approach. Last, there is a significant need for updated cost-effectiveness research to identify best practices that may shape future policy and reimbursement for care of diabetic foot syndrome.

ARTICLE INFORMATION

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