Complete Summary

GUIDELINE TITLE

Diagnosis and treatment of diabetic foot infections.

BIBLIOGRAPHIC SOURCE(S)

Lipsky BA, Berendt AR, Deery HG, Embil JM, Joseph WS, Karchmer AW, Lefrock JL, Lew DP, Mader JT, Norden C, Tan JS. Diagnosis and treatment of diabetic foot infections. Clin Infect Dis 2004 Oct 1;39(7):885-910. [290 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Diabetic foot infections

GUIDELINE CATEGORY

Diagnosis
Evaluation
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases

Internal Medicine
Podiatry

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To help reduce the medical morbidity, psychological distress, and financial costs associated with diabetic foot infections
- To provide a guideline on managing the diabetic patient with suspected or evident foot infection

TARGET POPULATION

Individuals diagnosed with diabetes

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Evaluation on three levels: the patient, wound, and infection
2. Determining the severity of the infection
    - History and physical examination
    - Serum chemistry analyses
    - Assessment of mental and psychological sate
    - Clinical foot exam and radiography
    - Foot pulses, blood pressures, duplex ultrasonography, and angiograms
    - Skin and soft-tissue examination and duplex ultrasonography
    - Light touch, monofilament pressure, or vibration perception
    - Inspect, debride, and probe the wound; radiography
    - Gram staining and culture, ultrasonography, or computed tomography (CT) for detection of deep abscesses, and radiography and/or magnetic resonance imaging (MRI) for detection of osteomyelitis

Treatment

1. Choose and initiate an empirical antimicrobial regimen
2. Determine the need for hospitalization
3. Stabilize the patient
4. Determine the need for surgery
5. Formulate a wound-care plan
6. Consider adjunctive treatments
7. Follow-up care
    - Antibiotic regimen
    - Reevaluate the wound
    - Review the off-loading and wound care regimens
    - Evaluate glycemic control
8. Consideration of osteomyelitis
    - Additional imaging studies

    - Empirical treatment
    - Bone biopsy
9. Patient education for future prevention

MAJOR OUTCOMES CONSIDERED

- Severe morbidities
- Amputation
- Hospital length of stay
- Financial burden

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline committee conducted an extensive literature search (which included the MEDLINE database, the EBSCO database, the Cochrane Library, diabetic foot Web sites and bibliographies, and hand-searching of bibliographies of published articles).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence

I. Evidence from ≥1 properly randomized, controlled trial
II. Evidence from ≥1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from >1 center); from multiple time-series; or from dramatic results from uncontrolled experiments
III. Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Committee members reviewed and discussed all available evidence in a series of meetings and established consensus through discussion and debate over a period of 3 years.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Three subcommittees drafted subsections that were modified and exchanged; these served as a basis for the final document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendation

A. Good evidence to support a recommendation for use; should always be offered
B. Moderate evidence to support a recommendation for use; should generally be offered
C. Poor evidence to support a recommendation; optional
D. Moderate evidence to support a recommendation against use; should generally not be offered
E. Good evidence to support a recommendation against use; should never be offered

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The final document underwent numerous revisions that were based on both internal and external reviews.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the quality of the evidence (I-III) and strength of recommendation (A-E) are given at the end of the "Major Recommendations" field.

1. Foot infections in patients with diabetes cause substantial morbidity and frequent visits to health care professionals and may lead to amputation of a lower extremity.
2. Diabetic foot infections require attention to local (foot) and systemic (metabolic) issues and coordinated management, preferably by a multidisciplinary foot-care team (**A-II**). The team managing these infections should include, or have ready access to, an infectious disease specialist or a medical microbiologist (**B-II**).
3. The major predisposing factor to these infections is foot ulceration, which is usually related to peripheral neuropathy. Peripheral vascular disease and various immunological disturbances play a secondary role.
4. Aerobic gram-positive cocci (especially *Staphylococcus aureus*) are the predominant pathogens in diabetic foot infections. Patients who have chronic wounds or who have recently received antibiotic therapy may also be infected with gram-negative rods, and those with foot ischemia or gangrene may have obligate anaerobic pathogens.
5. Wound infections must be diagnosed clinically on the basis of local (and occasionally systemic) signs and symptoms of inflammation. Laboratory (including microbiological) investigations are of limited use for diagnosing infection, except in cases of osteomyelitis (**B-II**).
6. Send appropriately obtained specimens for culture prior to starting empirical antibiotic therapy in all cases of infection, except perhaps those that are mild and previously untreated (**B-III**). Tissue specimens obtained by biopsy, ulcer curettage, or aspiration are preferable to wound swab specimens (**A-I**).
7. Imaging studies may help diagnose or better define deep, soft-tissue purulent collections and are usually needed to detect pathological findings in bone. Plain radiography may be adequate in many cases, but magnetic resonance imaging (MRI) (in preference to isotope scanning) is more sensitive and specific, especially for detection of soft-tissue lesions (**A-I**).
8. Infections should be categorized by their severity on the basis of readily assessable clinical and laboratory features (**B-II**). Most important among these are the specific tissues involved, the adequacy of arterial perfusion, and the presence of systemic toxicity or metabolic instability. Categorization helps determine the degree of risk to the patient and the limb and, thus, the urgency and venue of management.
9. Available evidence does not support treating clinically uninfected ulcers with antibiotic therapy (**D-III**). Antibiotic therapy is necessary for virtually all infected wounds, but it is often insufficient without appropriate wound care.
10. Select an empirical antibiotic regimen on the basis of the severity of the infection and the likely etiologic agent(s) (**B-II**). Therapy aimed solely at aerobic gram-positive cocci may be sufficient for mild-to-moderate infections in patients who have not recently received antibiotic therapy (**A-II**). Broad-spectrum empirical therapy is not routinely required but is indicated for severe infections, pending culture results and antibiotic susceptibility data (**B-III**). Take into consideration any recent antibiotic therapy and local antibiotic susceptibility data, especially the prevalence of methicillin-resistant *S. aureus* (MRSA) or other resistant organisms. Definitive therapy should be based on both the culture results and susceptibility data and the clinical response to the empirical regimen (**C-III**).

11. There is only limited evidence with which to make informed choices among the various topical, oral, and parenteral antibiotic agents. Virtually all severe and some moderate infections require parenteral therapy, at least initially (**C-III**). Highly bioavailable oral antibiotics can be used in most mild and in many moderate infections, including some cases of osteomyelitis (**A-II**). Topical therapy may be used for some mild superficial infections (**B-I**).
12. Continue antibiotic therapy until there is evidence that the infection has resolved but not necessarily until a wound has healed. Suggestions for the duration of antibiotic therapy are as follows: for mild infections, 1-2 weeks usually suffices, but some require an additional 1-2 weeks; for moderate and severe infections, usually 2-4 weeks is sufficient, depending on the structures involved, the adequacy of debridement, the type of soft-tissue wound cover, and wound vascularity (**A-II**); and for osteomyelitis, generally at least 4-6 weeks is required, but a shorter duration is sufficient if the entire infected bone is removed, and probably a longer duration is needed if infected bone remains (**B-II**).
13. If an infection in a clinically stable patient fails to respond to $\geq$1 antibiotic courses, consider discontinuing all antimicrobials and, after a few days, obtaining optimal culture specimens (**C-III**).
14. Seek surgical consultation and, when needed, intervention for infections accompanied by a deep abscess, extensive bone or joint involvement, crepitus, substantial necrosis or gangrene, or necrotizing fasciitis (**A-II**). Evaluating the limb's arterial supply and revascularizing when indicated are particularly important. Surgeons with experience and interest in the field should be recruited by the foot-care team, if possible.
15. Providing optimal wound care, in addition to appropriate antibiotic treatment of the infection, is crucial for healing **(A-I**). This includes proper wound cleansing, debridement of any callus and necrotic tissue, and, especially, off-loading of pressure. There is insufficient evidence to recommend use of a specific wound dressing or any type of wound healing agents or products for infected foot wounds.
16. Patients with infected wounds require early and careful follow-up observation to ensure that the selected medical and surgical treatment regimens have been appropriate and effective (**B-III**).
17. Studies have not adequately defined the role of most adjunctive therapies for diabetic foot infections, but systematic reviews suggest that granulocyte colony-stimulating factors and systemic hyperbaric oxygen therapy may help prevent amputations (**B-I**). These treatments may be useful for severe infections or for those that have not adequately responded to therapy, despite correcting for all amenable local and systemic adverse factors.
18. Spread of infection to bone (osteitis or osteomyelitis) may be difficult to distinguish from noninfectious osteoarthropathy. Clinical examination and imaging tests may suffice, but bone biopsy is valuable for establishing the diagnosis of osteomyelitis, for defining the pathogenic organism(s), and for determining the antibiotic susceptibilities of such organisms (**B-II**).
19. Although this field has matured, further research is much needed. The committee especially recommends that adequately powered prospective studies be undertaken to elucidate and validate systems for classifying infection, diagnosing osteomyelitis, defining optimal antibiotic regimens in various situations, and clarifying the role of surgery in treating osteomyelitis **(A-III**).

Definitions

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Strength of Recommendation

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CLINICAL ALGORITHM(S)

The original guideline provides the following algorithms:

- Algorithm 1, part 1: Approach to treating a diabetic patient with a foot wound
- Algorithm 1, part 2: Approach to treating a diabetic with a foot infection
- Algorithm 1, part 3: Approach to assessing a diabetic patient with a foot infection who is not responding well to treatment
- Algorithm 2: Approach to selecting antibiotic therapy for a diabetic with a foot infection
- Algorithm 3: Evaluating a diabetic patient who has suspected osteomyelitis of the foot

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Use of this guideline may reduce the burdens (medical, financial, and ecological) associated with inappropriate practices, including those related to antibiotic prescribing, wound care, hospitalization decisions, diagnostic testing, surgical procedures, and adjunctive treatments.

POTENTIAL HARMS

Antibiotic use encourages antimicrobial resistance, incurs financial cost, and may cause drug-related adverse effects; its use is discouraged as therapy of uninfected ulcers.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The committee members realize that the realities of primary care practice and the scarcity of resources in some clinical situations will restrict the implementation of some of the recommended procedures and treatments. They believe, however, that in almost all settings, high-quality care is usually no more difficult to achieve or expensive than poor care and its consequences.
- Because of the relative paucity of randomized controlled trials or other high-quality evidence in this field, most of the recommendations are based on discussion and consensus. Thus, the guideline committee elected to offer a relatively brief summary and to provide an extensive bibliography for those who would like to review the data themselves.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Lipsky BA, Berendt AR, Deery HG, Embil JM, Joseph WS, Karchmer AW, Lefrock JL, Lew DP, Mader JT, Norden C, Tan JS. Diagnosis and treatment of diabetic foot infections. Clin Infect Dis 2004 Oct 1;39(7):885-910. [290 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Oct 1

GUIDELINE DEVELOPER(S)

Infectious Diseases Society of America - Medical Specialty Society

SOURCE(S) OF FUNDING

Infectious Diseases Society of America (IDSA)

GUIDELINE COMMITTEE

Infectious Diseases Society of America (IDSA) Practice Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Benjamin A. Lipsky: Advisory board membership, research support from, or speaker's bureau for Pfizer, Merck, Wyeth-Ayerst, Cubist, Vicuron, and Ortho-McNeil.

Anthony R. Berendt: Speaker's bureau for Pfizer.

H. Gunner Deery: Speaker's bureau for GlaxoSmithKline and Pfizer, and research support from Theravance.

John M. Embil: Advisory board membership, research support from, or speaker's bureau for AstraZeneca, Bayer, Bristol-Myers Squibb, Eli Lilly, Fujisawa, Janssen Ortho, and Pfizer.

Warren S. Joseph: Consultant and speaker's bureau for Pfizer and Merck.

Adolf W. Karchmer: Research support from Bayer, Pfizer, Merck, Ortho-McNeil, Cubist, Pharmacia, Vicuron, and Fujisawa and advisory board for Aventis, Pfizer, King Pharmaceuticals, Chiron, Vicuron, Cubist, and Bayer.

Carl Norden: Former employee of Pfizer.

James S. Tan: Research support from and speaker's bureau for Wyeth, Merck, Pfizer, Ortho-McNeil, Bayer, and Glaxo-SmithKline.

Jack L. LeFrock and Daniel P. Lew: No conflict.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Infectious Disease Society of America (IDSA) Web site.

Print copies: Available from Infectious Diseases Society of America, 1300 Wilson Boulevard, Suite 300, Arlington, VA 22209.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Kish MA. Guide to development of practice guidelines. Clin Infect Dis 2001 Mar 15;32(6):851-4.

Electronic copies: Available from the Clinical Infectious Diseases Journal Web site.

Print copies: Available from Infectious Diseases Society of America, 1300 Wilson Boulevard, Suite 300, Arlington, VA 22209.

A PDA version of the original guideline document is available from www.idsaguidelinesforhandhelds.org.

PATIENT RESOURCES

None available

NGC STATUS

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