



Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria™ for imaging diagnosis of osteomyelitis in patients with diabetes mellitus.

BIBLIOGRAPHIC SOURCE(S)

Alazraki N, Dalinka MK, Berquist TH, Daffner RJ, De Smet AA, el-Khoury GY, Goergen TG, Keats TE, Manaster BJ, Newberg A, Pavlov H, Haralson RH, McCabe JB, Sartoris D. Imaging diagnosis of osteomyelitis in patients with diabetes mellitus. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun; 215(Suppl): 303-10. [20 references]

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SCOPE

DISEASE/CONDITION(S)

Osteomyelitis

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Nuclear Medicine
Orthopedic Surgery
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for patients with diabetes suspected of having osteomyelitis.

TARGET POPULATION

Patients with diabetes mellitus who are suspected of having osteomyelitis

INTERVENTIONS AND PRACTICES CONSIDERED

1. Plain x-ray
2. Ultrasound
3. Computed tomography
4. Nuclear Medicine
 - Gallium 67 scan
 - Indium leukocytes
 - 3-phase Tc99m bone scan
5. Magnetic resonance imaging
6. Invasive

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A comparative efficacy and cost-effectiveness analysis of four strategies for management of suspected pedal osteomyelitis in the setting of vascular impairment was reviewed. The four strategies considered were:

1. therapeutic trial of short-term antibiotics for presumed cellulitis without osteomyelitis (short)
2. technetium bone scanning followed by either short-term therapy if negative or either a biopsy or aggressive long-term intravenous therapy if positive (scan)
3. bone biopsy followed by long-term intravenous therapy if positive (biopsy)
4. immediate long-term intravenous antibiotics for presumed osteomyelitis (long)

It was concluded that over the whole range of prior probabilities, the short-term strategy was the least expensive. At very low probabilities, it dominated the other strategies. When the likelihood of osteomyelitis was higher (10%-20%), scanning resulted in outcomes and cost-effectiveness ratios comparable to those of immediate biopsy and was less invasive. When the probability of osteomyelitis was 50%, biopsy was quite cost effective compared with all the other strategies (cost-effectiveness ratio = \$15,502 per amputation) and was preferred to the scan strategy. When the confidence that a patient has osteomyelitis is very high (>90% probability), the improved outcomes associated with long-term antibiotics are achieved with little additional expense and with favorable cost-effectiveness ratios compared with those of the other strategies. Unfortunately, this study considered only Tc-99m bone scanning. The data we have in the literature indicates varying specificities and sensitivities for indium leukocyte studies and magnetic resonance imaging (MRI). However, most reports indicate values of 75%-100% sensitivities and 67%-95% specificities for both modalities. Cost is an important ingredient in the analyses reviewed, and therefore it is relevant to note that the indium leukocyte scan cost is about \$200-\$500 more than the Tc-99m bone scan (charged at about \$400), and the magnetic resonance imaging scan costs about \$600-\$900 more than the bone scan.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria™

Clinical Condition: Suspect Osteomyelitis in Patients with Diabetes Mellitus

Variant 1: Soft tissue ulceration with exposed bone.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Plain x-ray	9	Plain x-ray is appropriate to define bony complications (trauma, degenerative disease, changes from infection affecting bone, if they exist) and to provide a baseline.
Ultrasound	1	
Computed tomography	1	
Nuclear Medicine		
• Gallium 67 scan	1	
• Indium leukocytes	1	
• 3-phase Tc99m bone scan	1	
Magnetic resonance imaging	No Consensus	No consensus reached on independent voting rounds, but panel recognizes that when soft tissue ulceration exposes bone, no imaging is needed to affirm diagnosis of infection involving bone.
<p><u>Appropriateness Criteria Scale</u></p> <p>1 2 3 4 5 6 7 8 9</p> <p>1=Least appropriate 9=Most appropriate</p>		

Variant 2: Soft tissue ulceration with no exposed bone.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Plain x-ray	9	Plain x-ray is appropriate to define any bony abnormalities and to provide a baseline.
Ultrasound	1	
Computed tomography	1	

Nuclear Medicine		
• Gallium 67 scan	1	
• Indium leukocytes	No Consensus	Although the panel did not reach consensus on independent voting rounds, participants at discussion meeting recognized that in diabetic patients with soft tissue ulceration, either magnetic resonance imaging or indium-111 leukocyte imaging to diagnose osteomyelitis is acceptable.
• 3-phase Tc99m bone scan	No Consensus	
Magnetic resonance imaging	No Consensus	Although the panel did not reach consensus on independent voting rounds, participants at discussion meeting recognized that in diabetic patients with soft tissue ulceration, either magnetic resonance imaging or indium leukocyte imaging to diagnose osteomyelitis is acceptable.
<u>Appropriateness Criteria Scale</u> 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Clinical Condition: Suspect Osteomyelitis in Patients with Diabetes Mellitus

Variant 3: Inflamed soft tissue, no ulcer.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Plain x-ray	9	
Ultrasound	1	
Computed tomography	1	

Nuclear Medicine		
• Gallium 67 scan	1	
• Indium leukocytes	No Consensus	Although no consensus was reached by panel on independent voting rounds, the panel participants at discussion meeting recognized that in diabetic patients with inflamed soft tissue, but no ulcer, following plain x-ray to define other bony complications (i.e., neuroarthropathy, trauma, degenerative changes), either magnetic resonance imaging or indium leukocyte imaging is acceptable for assessment of possible bone infection.
• 3-phase Tc99m bone scan	No Consensus	If x-ray shows no bony complications, a 3-phase bone scan is also acceptable.
Magnetic resonance imaging	No Consensus	Although no consensus was reached by panel on independent voting rounds, the panel participants at discussion meeting recognized that in diabetic patients with inflamed soft tissue, but no ulcer, following plain x-ray to define other bony complications (i.e., neuroarthropathy, trauma, degenerative changes), either magnetic resonance imaging or indium leukocyte imaging is acceptable for assessment of possible bone infection.
<u>Appropriateness Criteria Scale</u> 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Clinical Condition: Suspected Osteomyelitis in Patients with Diabetes Mellitus

Variant 4: Persistently painful foot, but no ulcer or inflammation evident.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Plain x-ray	9	
Ultrasound	1	
Computed tomography	1	
Nuclear Medicine		
<ul style="list-style-type: none"> Indium leukocytes 	1	
<ul style="list-style-type: none"> Gallium 67 Scan 	1	
<ul style="list-style-type: none"> 3-phase Tc99m bone scan 	No Consensus	<p>Although no consensus was reached by the panel on independent voting rounds, at the discussion meeting, participants concurred that in diabetic patients with persistently painful foot, but no ulcer or inflammation evident, either magnetic resonance imaging or indium leukocyte imaging was acceptable to assess possible bone infection. Plain x-ray is indicated to define other bony complications such as trauma, degenerative disease, or neuroarthropathy that may alter other scan results. In case of no other bony abnormalities, 3-phase bone scan is also acceptable.</p>
Magnetic resonance imaging	No Consensus	<p>Although no consensus was reached by the panel on independent voting rounds, at the discussion meeting, participants concurred that in diabetic patients with persistently painful foot, but no ulcer or inflammation evident, either MRI or indium leukocyte imaging was acceptable to assess possible bone infection. Plain x-ray is indicated to define other bony complications such as trauma, degenerative disease, or neuroarthropathy that may alter other scan results. In case of no other bony abnormalities, 3-phase</p>

		bone scan is also acceptable.
Invasive	No Consensus	
<u>Appropriateness Criteria Scale</u> 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Clinical Condition: Osteomyelitis in Patients with Diabetes Mellitus

Variant 5: Suspect osteomyelitis, plain film neuroarthropathy.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Ultrasound	1	Plain x-ray is also acceptable to define neuroarthropathic abnormalities for correlation in interpreting other imaging.
Computed tomography	1	
Nuclear Medicine		
<ul style="list-style-type: none"> 3-Phase Tc99m bone scan 	1	
<ul style="list-style-type: none"> Gallium 67 scan 	1	
<ul style="list-style-type: none"> Indium leukocytes 	No Consensus	Although no consensus was reached by the panel on independent voting rounds, at the discussion meeting, the participants concurred that either magnetic resonance imaging or indium leukocyte scans was acceptable to assess osteomyelitis.
Plain x-ray	No Consensus	
Invasive	No Consensus	
Magnetic resonance imaging	No Consensus	Although no consensus was reached by the panel on independent voting rounds, at the discussion meeting, the participants concurred that either magnetic resonance imaging

		or indium leukocyte scans was acceptable to assess osteomyelitis.
<u>Appropriateness Criteria Scale</u> 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 6: Suspect osteomyelitis, plain film no evidence of degenerative change, prior trauma and no history of prior infection.

Radiologic Exam Procedure	Appropriateness Rating	Comments
Ultrasound	1	
Computed tomography	1	
Nuclear Medicine		
<ul style="list-style-type: none"> Gallium 67 scan 	1	
<ul style="list-style-type: none"> Indium leukocytes 	No Consensus	Although no consensus was reached by the panel on independent voting rounds, at the discussion meeting, the participants concurred that 3-phase bone scan, magnetic resonance imaging, or indium leukocyte scan was acceptable to diagnose osteomyelitis.
<ul style="list-style-type: none"> 3-phase Tc99m bone scan 	No Consensus	
Plain x-ray	No Consensus	
Magnetic resonance imaging	No Consensus	
<u>Appropriateness Criteria Scale</u> 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Conclusion

Diabetic foot infections account for 20% of all diabetic patient hospital admissions in the United States. Complications of diabetic foot infections lead to close to half of all nontraumatic foot or leg amputations. Thus, appropriate and adequate early treatment is often critical to avoid loss of limb in diabetics presenting with foot infections. Appropriate treatment depends on accurate diagnosis, which often in diabetic foot infection relates to distinguishing between cellulitis and osteomyelitis. Noninvasive diagnostic imaging is greatly preferred since surgical exploration of a foot scan leads to unnecessary damage, particularly in a neuropathic diabetic foot.

Diabetics who present with foot infections and osteomyelitis require intravenous antibiotics. If the infection is confined to soft tissue, a simple course of short-term antibiotics and good wound care, if ulceration is present, may be all that is needed. Management varies widely from options that may include clinical diagnosis and a trial of antibiotics if osteomyelitis is considered unlikely, to vigorous pursuit of a diagnosis using plain film x-rays, bone scans, indium labeled leukocyte scans, magnetic resonance imaging, and/or a bone biopsy to positively diagnose osteomyelitis.

In conclusion, the data for adults with diabetes and foot ulcers or suspected osteomyelitis suggest comparability between indium leukocytes and magnetic resonance imaging for diagnosing osteomyelitis, but cost considerations may slightly favor the less expensive indium leukocyte test.

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate selection of radiologic exam procedures to evaluate patients with diabetes mellitus suspected of osteomyelitis.

POTENTIAL HARMS

None identified

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Alazraki N, Dalinka MK, Berquist TH, Daffner RJ, De Smet AA, el-Khoury GY, Goergen TG, Keats TE, Manaster BJ, Newberg A, Pavlov H, Haralson RH, McCabe JB, Sartoris D. Imaging diagnosis of osteomyelitis in patients with diabetes mellitus. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun; 215(Suppl): 303-10. [20 references]

ADAPTATION

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

DATE RELEASED

1995 (revised 1999)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria™.

GUIDELINE COMMITTEE

ACR Appropriateness Criteria™ Committee, Expert Panel on Musculoskeletal Imaging.

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of Panel Members: Naomi Alazraki, MD; Murray K. Dalinka, MD; Thomas H. Berquist, MD; Richard H. Daffner, MD; Arthur A. DeSmet, MD; George Y. El-Khoury, MD; Thomas G. Goergen, MD; Theodore E. Keats, MD; B.J. Manaster, MD, PhD; Arthur Newberg, MD; Helene Pavlov, MD; Robert H. Haralson, III, MD; John B. McCabe, MD; David Sartoris, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It is a revision of a previously issued version (Appropriateness criteria for imaging diagnosis of osteomyelitis in patients with diabetes mellitus. Reston [VA]: American College of Radiology (ACR); 1995. 8 p. [ACR Appropriateness Criteria™]).

The ACR Appropriateness Criteria™ are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence. The next review date for this topic is 2004.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [American College of Radiology \(ACR\) Web site](#).

Print copies: Available from ACR, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 6, 2001. The information was verified by the guideline developer as of June 29, 2001.

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