

**American College of Radiology
ACR Appropriateness Criteria®**

Clinical Condition: Suspected Osteomyelitis of the Foot in Patients with Diabetes Mellitus

Variant 1: Soft-tissue swelling without neuropathic arthropathy or ulcer.

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary, and both are indicated. The results of initial x-ray examination do not preclude the necessity for additional studies.	☼
MRI foot without and with IV contrast	9	Radiographs and MRI are complementary, and both are indicated. MRI is useful preoperatively to identify the extent of involvement and to map devitalized areas.	O
MRI foot without IV contrast	9	Radiographs and MRI are complementary, and both are indicated.	O
Labeled leukocyte scan foot (In-111 or Tc-99m)	3	May be appropriate in certain circumstances such as if MRI is contraindicated or unavailable.	☼ ☼ ☼ ☼
Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) foot	1		☼ ☼ ☼ ☼
Tc-99m 3-phase bone scan foot	1		☼ ☼ ☼
Labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot	1		☼ ☼ ☼ ☼
Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot	1		☼ ☼ ☼ ☼
US foot	1		O
CT foot without IV contrast	1		☼
CT foot without and with IV contrast	1		☼
CT foot with IV contrast	1		☼
FDG-PET/CT foot	1		☼ ☼ ☼ ☼
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition: Suspected Osteomyelitis of the Foot in Patients with Diabetes Mellitus

Variant 2: Soft-tissue swelling with neuropathic arthropathy without ulcer.

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary, and both are indicated. The results of initial x-ray examination do not preclude the necessity for additional studies.	⊕
MRI foot without and with IV contrast	9	Radiographs and MRI are complementary, and both are indicated. MRI is useful preoperatively to identify the extent of involvement and to map devitalized areas.	O
MRI foot without IV contrast	9	Radiographs and MRI are complementary, and both are indicated.	O
CT foot without IV contrast	5	For neuropathy or if MRI contraindicated.	⊕
Labeled leukocyte scan foot (In-111 or Tc-99m)	3	May be appropriate in certain circumstances such as if MRI is contraindicated or unavailable.	⊕ ⊕ ⊕ ⊕
Labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot	3	May be appropriate in selected clinical circumstances.	⊕ ⊕ ⊕ ⊕
CT foot without and with IV contrast	1		⊕
CT foot with IV contrast	1		⊕
Tc-99m 3-phase bone scan foot	1		⊕ ⊕ ⊕
Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) foot	1		⊕ ⊕ ⊕ ⊕
Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot	1		⊕ ⊕ ⊕ ⊕
US foot	1		O
FDG-PET/CT foot	1		⊕ ⊕ ⊕ ⊕
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition: Suspected Osteomyelitis of the Foot in Patients with Diabetes Mellitus

Variant 3: Soft-tissue swelling without neuropathic arthropathy with ulcer.

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary, and both are indicated. The results of initial x-ray examination do not preclude the necessity for additional studies.	☼
MRI foot without and with IV contrast	9	Radiographs and MRI are complementary, and both are indicated. MRI is useful preoperatively to identify the extent of involvement and to map devitalized areas.	O
MRI foot without IV contrast	9	Radiographs and MRI are complementary, and both are indicated.	O
Labeled leukocyte scan foot (In-111 or Tc-99m)	3	May be appropriate in certain circumstances such as if MRI is contraindicated or unavailable.	☼ ☼ ☼ ☼
Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) foot	1		☼ ☼ ☼ ☼
Tc-99m 3-phase bone scan foot	1		☼ ☼ ☼
Labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot	1		☼ ☼ ☼ ☼
Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot	1		☼ ☼ ☼ ☼
US foot	1		O
CT foot without IV contrast	1		☼
CT foot without and with IV contrast	1		☼
CT foot with IV contrast	1		☼
FDG-PET/CT foot	1		☼ ☼ ☼ ☼
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Clinical Condition: Suspected Osteomyelitis of the Foot in Patients with Diabetes Mellitus

Variant 4: Soft-tissue swelling with neuropathic arthropathy and ulcer.

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary, and both are indicated. The results of initial x-ray examination do not preclude the necessity for additional studies.	⊕
MRI foot without and with IV contrast	9	Radiographs and MRI are complementary, and both are indicated. MRI is useful preoperatively to identify the extent of involvement and to map devitalized areas.	O
MRI foot without IV contrast	9	Radiographs and MRI are complementary, and both are indicated.	O
Labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot	3		⊕ ⊕ ⊕ ⊕
Labeled leukocyte scan foot (In-111 or Tc-99m)	1		⊕ ⊕ ⊕ ⊕
Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) foot	1		⊕ ⊕ ⊕ ⊕
Tc-99m 3-phase bone scan foot	1		⊕ ⊕ ⊕
Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot	1		⊕ ⊕ ⊕ ⊕
CT foot without IV contrast	1		⊕
CT foot without and with IV contrast	1		⊕
CT foot with IV contrast	1		⊕
US foot	1		O
FDG-PET/CT foot	1		⊕ ⊕ ⊕ ⊕
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

SUSPECTED OSTEOMYELITIS OF THE FOOT IN PATIENTS WITH DIABETES MELLITUS

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Summary of Literature Review

Introduction/Background

Throughout the last 50 years there has been much written about the diabetic foot, with little consensus as to whether, when, and what imaging is appropriate. This overview summarizes the literature and makes recommendations for imaging based on the available data. It is important to emphasize that in diabetics, virtually all foot osteomyelitis is due to direct spread from an adjacent soft-tissue infection, not from hematogenous seeding [1]. Accordingly, this review discusses several clinical situations in which osteomyelitis or diabetic pedal disease is suspected but clinical findings differ because of the presence or absence of soft-tissue swelling, ulceration, and neuropathy.

Note that although several of the variants have similar recommendations, they present as unique clinical scenarios.

Soft-Tissue Swelling without Neuropathic Arthropathy or Ulcer

The probability of having osteomyelitis in a diabetic foot without evidence of ulceration of the adjacent soft tissue is extremely low [1]. Whether there is or is not soft-tissue swelling, these patients have almost no incidence of osteomyelitis and a low incidence of septic arthritis, but some frequency of soft-tissue infections [2]. The only situation in which such a patient can have osteomyelitis is the presence of a “hidden” ulcer that has granulated over and may appear healed. In that situation the risk of osteomyelitis is still extremely low, since the ulcer would not have granulated over if osteomyelitis were present [3]. Therefore, without a clinically apparent ulcer, the role of imaging may be to diagnose neuropathic disease or to confirm the presence of soft-tissue infection, establish its extent, and identify any associated complications (eg, abscess, foreign matter).

Soft-Tissue Swelling with Neuropathic Arthropathy without Ulcer

A more difficult question is whether soft-tissue swelling is the result of neuropathic arthropathy or soft-tissue infection (with or without osteomyelitis) [4,5]. In a patient who has neuropathic arthropathy, the risk of infection is usually low if there is no ulceration. Radiography can be used as a screening examination; however, computed tomography (CT) can identify neuropathic arthropathy that may be radiographically occult and may be the cause of the swelling and pain (mimicking infection). CT cannot reliably exclude osteomyelitis. The use of positron emission tomography with CT (PET/CT) for diagnosing diabetic pedal osteomyelitis has been studied, but the data are limited and contradictory, and its role is currently uncertain [6-9].

Bone scintigraphy is indeterminate in the diagnosis of osteomyelitis; however, a negative bone scan excludes infection with a high degree of certainty [10-14]. Indium white blood cell (WBC) scintigraphy, in general, is more

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accurate [15]. A negative indium WBC study strongly supports the absence of infection [14]. Since labeled leukocytes accumulate in the uninfected neuropathic joint [15,16], performing complementary technetium-99m sulfur colloid bone marrow imaging facilitates the differentiation of labeled leukocyte uptake due to bone marrow from that due to infection [16]. Magnetic resonance imaging (MRI) generally has the best clinical results in this scenario with or without contrast [17-21], but the yield is going to be low in this group of patients.

The early diagnosis of neuropathic disease prior to the development of radiographic change is important, as these patients will be treated with altered footwear and orthotics to prevent the progression to deformity. Scintigraphy is, however, extremely sensitive to early neuropathic disease, long before radiographic changes are present. MRI is less sensitive but is a better test if there is a possibility of soft-tissue infection. A report noted increased low-level hypermetabolic activity on PET/CT in neuropathic arthropathy, easily distinguishing it from the normal foot and the infected neuropathic arthropathy [7], although other reports note PET/CT as indeterminate [8,9].

Soft-Tissue Swelling with Ulcer Extending to Bone

If an ulcer is present, the risk of infection is high (12%-20%) [22,23]. If the bone is exposed or if the ulcer extends to bone (positive probe-to-bone test), the likelihood of osteomyelitis is even greater (20%-66%), though how much greater depends on the pretest probability in the population studied [19,22-24]. In general, a positive probe-to-bone test is of moderate predictive value [19]. A negative test, however, may exclude the diagnosis of osteomyelitis with a high negative predictive value [19,22]. The role of imaging in these patients is to confirm the presence of infection and show its extent. Radiographic features will vary with the virulence and extent of the infection, but generally will not become positive for several days to weeks following infection. While a negative bone scan excludes osteomyelitis, a positive study is quite nonspecific [11,25]. Surprisingly, indium-labeled WBC scan, even when combined with sulfur colloid marrow imaging, has low specificity [26-28], although if the ulcer is away from the joint, these techniques are better. MRI has high specificity and sensitivity both with and without contrast [4,17,19,21,29,30], although intravenous contrast is especially useful to identify associated complications [20,31,32]. Ultrasound (US) may have promise in long bones but, to date, data about its utility in diagnosing the diabetic foot are quite limited. The role of fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG)-PET is still evolving, and comparisons of its value in diagnosing osteomyelitis with that of MRI have yielded conflicting results [7,8].

Neuropathic Arthropathy with Ulcer Extending to Bone

In patients who have diabetes and secondary neuropathic arthropathy, the infection is usually over an osseous abnormality with an ulcer. If the ulcer tracks down to bone, the risk of osteomyelitis is high, perhaps even higher than in the preceding situation where there is an ulcer without neuropathic arthropathy. The overall role of imaging therefore, is more to determine the extent of the disease than to definitively diagnose it [33]. Most authors do not advocate scintigraphy in this situation because of its relatively poor spatial resolution for extent of disease; similar conclusions apply to PET [25].

Indium-labeled WBC scanning with bone marrow scanning accurately diagnoses osteomyelitis in the neuropathic foot but is poor at showing the anatomic extent of infection [16]. Radiography has a high specificity but low sensitivity. US is unproven. CT will show the neuropathic arthropathy disease but not much else. MRI should be performed to determine extent of disease [1]. Intravenous contrast is especially useful to identify associated complications, such as complex fluid collections, abscesses, or nonvascularized tissue, information that is also important for surgical planning. [20,31,32].

Summary

- If a patient has an ulcer that extends to bone, osteomyelitis is quite likely but not invariably present.
- If there is no ulcer and there is still a clinical suspicion of infection, MRI is the test of choice.
- Conventional radiographs should be done simultaneously in both situations.
- When imaging is indeterminate, aspiration/biopsy should be considered.

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the

long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document.

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
○	0 mSv	0 mSv
⊗	<0.1 mSv	<0.03 mSv
⊗ ⊗	0.1-1 mSv	0.03-0.3 mSv
⊗ ⊗ ⊗	1-10 mSv	0.3-3 mSv
⊗ ⊗ ⊗ ⊗	10-30 mSv	3-10 mSv
⊗ ⊗ ⊗ ⊗ ⊗	30-100 mSv	10-30 mSv

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as “Varies”.

Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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The 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 examinations 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 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.