

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

Clinical Condition: Suspected Osteomyelitis in Patients with Diabetes Mellitus

Variant 1: Soft-tissue edema without ulcer or neuroarthropathy.

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary. Both are indicated.	Min
MRI foot with contrast	9	Radiographs and MRI are complementary. Both are indicated. Useful for mapping devitalized areas preoperatively. See comments regarding contrast in text under "Anticipated Exceptions."	None
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	None
NUC Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	High
NUC Tc-99m 3-phase bone scan foot	1		Med
NUC In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
NUC Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
US foot	1		None
CT foot without contrast	1		Min
FDG-PET foot	1		High
<u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

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Clinical Condition:**Suspected Osteomyelitis in Patients with Diabetes Mellitus****Variant 2:****Ulcer with no exposed bone without neuroarthropathy.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary. Both are indicated.	Min
MRI foot with contrast	9	Radiographs and MRI are complementary. Both are indicated. Useful for mapping devitalized areas preoperatively. See comments regarding contrast in text under "Anticipated Exceptions."	None
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	None
NUC Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	High
NUC Tc-99m 3-phase bone scan foot	1		Med
NUC In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
NUC Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
US foot	1		None
CT foot without contrast	1		Min
FDG-PET foot	1		High
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Variant 3:**Ulcer with exposed bone without neuroarthropathy.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary. Both are indicated.	Min
MRI foot with contrast	9	Radiographs and MRI are complementary. Both are indicated. Useful for mapping devitalized areas preoperatively. See comments regarding contrast in text under "Anticipated Exceptions."	None
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	None
NUC Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	High
NUC Tc-99m 3-phase bone scan foot	1		Med
NUC In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
NUC Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
US foot	1		None
CT foot without contrast	1		Min
FDG-PET foot	1		High
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Clinical Condition:**Suspected Osteomyelitis in Patients with Diabetes Mellitus****Variant 4:****Neuropathy without ulcer.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary. Both are indicated.	Min
MRI foot with contrast	9	Radiographs and MRI are complementary. Both are indicated. See comments regarding contrast in text under "Anticipated Exceptions."	None
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	None
CT foot without contrast	5	For neuropathy or if MRI contraindicated.	Min
NUC Tc-99m 3-phase bone scan foot	5	Useful for pre-radiographic findings of neuropathy. Also if MRI contraindicated.	Med
NUC Tc-99m 3-phase bone scan and In-111 WBC scan foot	2		High
NUC In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
NUC Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
US foot	1		None
FDG-PET foot	1		High
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Variant 5:**Neuroarthropathy with ulcer without exposed bone.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary. Both are indicated.	Min
MRI foot with contrast	9	Radiographs and MRI are complementary. Both are indicated. See comments regarding contrast in text under "Anticipated Exceptions."	None
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	None
NUC Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	High
NUC Tc-99m 3-phase bone scan foot	1		Med
NUC In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
NUC Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
CT foot without contrast	1		Min
US foot	1		None
FDG- PET foot	1		High
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

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Clinical Condition:**Suspected Osteomyelitis in Patients with Diabetes Mellitus****Variant 6:****Neuroarthopathy with ulcer with exposed bone.**

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
X-ray foot	9	Initial study. Radiographs and MRI are complementary. Both are indicated.	Min
MRI foot with contrast	9	Radiographs and MRI are complementary. Both are indicated. See comments regarding contrast in text under "Anticipated Exceptions."	None
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	None
NUC Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	High
NUC Tc-99m 3-phase bone scan foot	1		Med
NUC In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
NUC Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		High
CT foot without contrast	1		Min
US foot	1		None
FDG-PET foot	1		High
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

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SUSPECTED OSTEOMYELITIS IN PATIENTS WITH DIABETES MELLITUS

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Summary of Literature Review

Through 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 will summarize some of the work and draw conclusions based on the available data. We will discuss several clinical situations in which osteomyelitis or diabetic pedal disease is suspected but clinical findings differ because of the presence or absence of edema ulceration and neuropathy.

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

Soft-Tissue Edema without Ulceration

First, the probability of having osteomyelitis in a diabetic foot without evidence of ulceration 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 might be to diagnose neuropathic disease or to see if there is soft-tissue infection only [3].

Neuropathy without Ulcer

A more difficult question is whether it is the neuroarthropathy or the soft-tissue infection that is causing the soft-tissue swelling [4,5]. In a patient who has

neuroarthropathy, the risk of infection is usually low without ulceration. Radiography can be used as a screening examination. Computed tomography (CT) may pick up neuroarthropathy, which may not be apparent radiographically and may be the cause of the swelling and pain (mimicking infection). CT can rarely exclude the diagnosis of osteomyelitis definitively if there is no edema in the marrow (fat is visible).

Scintigraphy is of indeterminate insensitivity and specificity, whether it is bone scan, indium or indium with sulfur colloid, or even positron emission tomography (PET) [6-9]. Flow images are the best discriminators of infection, but remain imperfect. Magnetic resonance imaging (MRI) likely has the best clinical results in this scenario with or without contrast, but the yield is going to be low in this clinical group of patients, and it is costly [10].

There is some importance in diagnosing neuropathic disease prior to radiographic changes, 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.

Ulcer with Exposed Bone

If an ulcer is present, the risk of infection is quite high, and almost invariable if the ulcer reaches bone. The role of imaging would be to confirm the infection and show extent. Radiography will show the infection, however late. Bone scan is quite nonspecific [7,11]. Surprisingly, indium scan, even when combined with sulfur colloid marrow imaging, has low specificity [12-14], although if the ulcer is away from the joint these techniques are better. MRI has high specificity and sensitivity both with and without contrast [15]. Ultrasound (US) may have promise in long bones but, to date, data about its utility in diagnosing the diabetic foot are quite limited. PET results are similarly poor, as this technique shows metabolic activity primarily and therefore is not specific [16].

Ulcer with Neuropathy and Exposed Bone

In patients who have diabetes and secondary neuroarthropathy, the infection is usually over an osseous abnormality with an ulcer. If the ulcer tracks down to bone, the risk of osteomyelitis is extremely high, perhaps even higher than in the preceding situation where there is an ulcer without neuropathic deformity. The overall role of imaging therefore, is more to determine the extent of the disease than to definitively diagnose it [17]. Therefore, most authors do not advocate scintigraphy in this situation because of its relative poor spatial resolution

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for extent of disease; similar conclusions apply to PET [11].

Similarly, indium-labeled WBC (white blood cell) scanning with or without bone marrow scanning has only mixed sensitivity and specificity for osteomyelitis with neuropathy and yields poor anatomic extent of infection. Radiography has a high specificity but low sensitivity. US is unproven. CT will show the neuroarthropathic disease but not much else. MRI should be performed to determine extent of disease [1]. T1 and fat-suppressed sequences are complementary, and contrast may or may not be used. The use of contrast is more to see the extent of the disease as well as the extent of vascularity, rather than to diagnose infections [10]. Contrast may also help identify necrotic or poorly perfused regions, and to aid in surgical planning [18,19].

Summary and Recommendations

If a patient has an ulcer that extends to bone, there is quite likely, but not invariably, osteomyelitis. The best way to confirm this diagnosis and determine the extent of disease is with MRI. If there is no ulcer and there is still a clinical suspicion of infection, MRI is the test of choice. However, conventional radiographs should be done simultaneously in both situations. In indeterminate cases, aspiration and biopsy would be the next step.

If there is soft-tissue swelling the question is, “Is there early neuropathic disease or infection present?” Radiographs should be performed first. If the radiographs are normal, another test should be performed. If the suspicion of infection is low, the next test should probably be a three-phase bone scan. If there is a modest risk of infection, MRI is probably indicated.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF), also known as nephrogenic fibrosing dermopathy) was first identified in 1997 and has recently generated substantial concern among radiologists, referring doctors and lay people. Until the last few years, gadolinium-based MR contrast agents were widely believed to be almost universally well tolerated, extremely safe and non-nephrotoxic, even when used in patients with impaired renal function. All available experience suggests that these agents remain generally very safe, but recently some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed NSF [20-22], a syndrome that can be fatal. Further studies are necessary to determine what the exact relationships are between gadolinium-containing contrast agents, their specific components and stoichiometry, patient renal function and NSF. Current theory links the development of NSF to the administration of relatively high doses (eg, >0.2mM/kg) and to agents in which the gadolinium is least strongly chelated. The FDA has recently issued a “black box” warning concerning these contrast agents

(http://www.fda.gov/cder/drug/InfoSheets/HCP/gcca_200705HCP.pdf).

This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated GFR <30 mL/min/1.73m²), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s) [21].

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. 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	Effective Dose Estimate Range
None	0
Minimal	< 0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

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