American College of Radiology
ACR Appropriateness Criteria®

Clinical Condition: **Suspected Osteomyelitis of the Foot 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.	☢
MRI foot without and with contrast	9	Radiographs and MRI are complementary. Both are indicated. Useful for mapping devitalized areas preoperatively. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	O
Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan foot	1		☢ ☢ ☢
In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
US foot	1		O
CT foot without contrast	1		☢
FDG-PET 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: **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.	☢
MRI foot without and with contrast	9	Radiographs and MRI are complementary. Both are indicated. Useful for mapping devitalized areas preoperatively. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	O
Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan foot	1		☢ ☢ ☢
In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
US foot	1		O
CT foot without contrast	1		☢
FDG-PET foot	1		☢ ☢ ☢ ☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually 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.	☢
MRI foot without and with contrast	9	Radiographs and MRI are complementary. Both are indicated. Useful for mapping devitalized areas preoperatively. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	O
Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan foot	1		☢ ☢ ☢
In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
US foot	1		O
CT foot without contrast	1		☢
FDG-PET 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: **Neuropathy without ulcer.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary. Both are indicated.	☢
MRI foot without and with contrast	9	Radiographs and MRI are complementary. Both are indicated. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	O
CT foot without contrast	5	For neuropathy or if MRI contraindicated.	☢
Tc-99m 3-phase bone scan foot	5	Useful for pre-radiographic findings of neuropathy. Also if MRI contraindicated.	☢ ☢ ☢
Tc-99m 3-phase bone scan and In-111 WBC scan foot	2		☢ ☢ ☢ ☢
In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
US foot	1		O
FDG-PET foot	1		☢ ☢ ☢ ☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually 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.	☢
MRI foot without and with contrast	9	Radiographs and MRI are complementary. Both are indicated. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	O
Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan foot	1		☢ ☢ ☢
In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
CT foot without contrast	1		☢
US foot	1		O
FDG- PET 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 6: **Neuroarthopathy with ulcer with exposed bone.**

Radiologic Procedure	Rating	Comments	RRL*
X-ray foot	9	Initial study. Radiographs and MRI are complementary. Both are indicated.	☢
MRI foot without and with contrast	9	Radiographs and MRI are complementary. Both are indicated. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI foot without contrast	9	Radiographs and MRI are complementary. Both are indicated.	O
Tc-99m 3-phase bone scan and In-111 WBC scan foot	4	If MRI contraindicated.	☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan foot	1		☢ ☢ ☢
In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
Tc-99m 3-phase bone scan and In-111 WBC scan and Tc-99m sulfur colloid marrow scan foot	1		☢ ☢ ☢ ☢
CT foot without contrast	1		☢
US foot	1		O
FDG-PET 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

Expert Panel on Musculoskeletal Imaging: Mark E. Schweitzer, MD[1]; Richard H. Daffner, MD[2]; Barbara N. Weissman, MD[3]; D. Lee Bennett, MD, MA[4]; Judy S. Blebea, MD[5]; Jon A. Jacobson, MD[6]; William B. Morrison, MD[7]; Charles S. Resnik, MD[8]; Catherine C. Roberts, MD[9]; David A. Rubin, MD[10]; Leanne L. Seeger, MD[11]; Mihra Taljanovic, MD[12]; James N. Wise, MD[13]; William K. Payne III, MD, MPH.[14]

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].

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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 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) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (ie, <30 mL/min/1.73m^2), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73m^2. For more information, please see the ACR *Manual on Contrast Media* [20].

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
O	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 NS (not specified).

Supporting Document(s)

- ACR Appropriateness Criteria® Overview
- Procedure Information
- Evidence table under review

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