Complete Summary

GUIDELINE TITLE

Suspected lower extremity deep vein thrombosis.

BIBLIOGRAPHIC SOURCE(S)

Polak JF, Yucel EK, Bettmann MA, Casciani T, Gomes AS, Grollman JH, Holtzman SR, Sacks D, Schoepf J, Stanford W, Jaff M, Moneta GL, Expert Panel on Cardiovascular Imaging. Suspected lower extremity deep vein thrombosis. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 5 p. [44 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Needleman L, Polak JF, Bettmann MA, Boxt LM, Gomes AS, Grollman J, Henkin RE, Higgins CB, Kelley MJ, Pagan-Marin H, Stanford W. Suspected lower extremity deep vein thrombosis. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):49-53.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 23, 2007, Gadolinium-based Contrast Agents: The addition of a boxed warning and new warnings about the risk of nephrogenic systemic fibrosis (NSF) to the full prescribing information for all gadolinium-based contrast agents (GBCAs).

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SCOPE

DISEASE/CONDITION(S)

Lower extremity deep vein thrombosis

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Geriatrics
Internal Medicine
Nuclear Medicine
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 suspected lower extremity deep vein thrombosis

TARGET POPULATION

Patients with suspected lower extremity deep vein thrombosis

INTERVENTIONS AND PRACTICES CONSIDERED

1. Ultrasound (US), Duplex Doppler compression
2. Magnetic resonance imaging (MRI), venography
3. Invasive (INV)

    - Venography, pelvic
    - Venography, lower extremity
4. Computed tomography (CT) (as an adjunct to CT pulmonary angiography [CTPA] for suspected pulmonary embolism [PE])
    - Pelvis, with contrast
    - Venography, lower extremity, (following arm injection)
5. Nuclear medicine (NUC), radionuclide venography (macroaggregated albumin [MAA])
6. Impedance plethysmography (IPG)
7. X-ray
8. Continuous Wave Doppler (nonimaging)

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 peer-reviewed medical journals, and the major applicable articles were identified and collected.

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

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

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. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. 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 percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by this Delphi technique, 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. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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

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.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Suspected Lower Extremity Deep Vein Thrombosis (DVT)

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, Duplex Doppler compression	9	
MRI, venography, lower extremity	6	Demonstrated to be useful, but insufficient supporting data so far.
INV, venography, pelvic	6	When other studies equivocal or an intervention is planned.
CT, pelvis, with contrast	6	As an adjunct to CTPA done for suspected PE
INV, venography, lower extremity	5	When other studies equivocal or an intervention is planned.
CT, venography, lower extremity, (following arm injection)	5	As an adjunct to CTPA done for suspected PE
NUC, Radionuclide venography (MAA), lower extremity	3	
IPG, lower extremity	2	
X-ray, lower extremity	2	
Continuous Wave Doppler (nonimaging), lower extremity	1	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

The patient with symptomatic acute deep vein thrombosis (DVT) in a leg vein presents either with local pain and tenderness or with edema and swelling of the lower extremity, although patients with extensive DVT may be completely

asymptomatic. Accuracy of the clinical diagnosis DVT is no better than 50%. Some of the pathological entities that mimic the signs and symptoms of acute DVT are Baker's cyst, cellulitis, lymphedema, chronic venous disease, and varied musculoskeletal disorders. The importance of diagnosing acute DVT lies mostly in its relationship to acute pulmonary embolism. Without treatment, pulmonary embolism is likely to occur in up to 50% of patients who have DVT of the lower extremity. Up to 30% of the episodes of pulmonary embolism can have death as an outcome. This can be significantly reduced--by a factor of 10--when the patient is treated with anticoagulation. The site of DVT is important since involvement of the popliteal and above-the-knee veins is strongly associated with the risk of pulmonary embolism. DVT involving only the calf veins is not associated with a high risk for pulmonary embolism. Symptomatic DVT isolated to the calf veins is also less common than DVT of the femoropopliteal system.

Various tests that are available for evaluating the patient include contrast venography, Doppler US, various radionuclide approaches, a plasma D-dimer test, magnetic resonance venography, and contrast computed tomographic venography (MRV). Diagnostic tests that have been discarded include nonimaging Doppler waveform analysis, thermography, and various iterations of plethysmography: impedance, strain and photo-plethysmography.

Imaging is a key component of diagnostic strategies used to determine the presence of lower extremity deep vein thrombosis (DVT). Lower extremity contrast venography is now rarely used in clinical practice, although it is still considered to be the "gold standard" examination. Noninvasive tests, with the exception of plasma D-dimer (due to high sensitivity but limited specificity for DVT), are used with the following consideration: a patient with a positive result on a noninvasive test is considered to have DVT and is treated. If the test gives a negative result, then the clinical suspicion of DVT is used to determine whether another test or the same test should be used to serially monitor the patient. If the repeated test becomes positive, the patient is treated. If the noninvasive test remains negative, it or another test may be repeated. The type of test, the number of repeat examinations, and the duration of serial monitoring vary. For example, patients who have only above-the-knee venous US studies may still have below-the-knee (calf) deep vein thrombi. A repeat US examination at 5 to 7 days has been proven to reliably diagnose patients with calf vein thrombi that extend into the above-the-knee veins. If this occurs, the patient is treated. If the test remains negative, the patient is considered not to have lower extremity DVT.

Contrast Venography

Contrast venography is the "gold-standard" examination. An iodine-containing contrast agent is injected into a foot vein. DVT is present if a distinct filling defect is present in a deep vein of the calf or thigh. Other findings, such as an abrupt cutoff, absence of filling or presence of collaterals, are less specific and may be related to technical factors or to chronic venous thrombosis. Although this examination serves as the "gold standard," it may not give reliable results in 5 to 10% of patients. It also carries some risks: contrast reaction, local irritation or skin loss due to extravasation, renal failure, and chemically induced thrombophlebitis.

Ultrasound Imaging

Ultrasound is now recognized as the most effective alternative to contrast venography for the detection of symptomatic venous thrombosis of the leg. During real-time imaging, the main diagnostic criterion is failure to compress the vein walls while pressure is applied to the skin. This approach has a very high sensitivity (95%) and a high specificity (98%) for the above-the-knee veins. The accuracy for detecting isolated calf vein thrombosis is not as well studied. Sensitivity is at least 90% for specificity above 90% if isolated calf vein thrombi are sought. Doppler waveform analysis is integrated with imaging US as either duplex US or color flow US. Color Doppler imaging may also help characterize the type of DVT as obstructive or partly obstructive. Although continuous-wave Doppler can be used without imaging, this requires considerable skill. This non-imaging approach has been supplanted by duplex and color flow imaging techniques. The real-time US examination is easy to perform, can be done at the bedside, and can be used for serial studies. It has a low technical failure rate. It is less consistent in diagnostic performance above the inguinal canal.

Tests of Limited Utility

Plethysmography was for a time considered the main approach to the noninvasive detection of DVT. It evaluates the filling and emptying characteristics of blood in the lower extremity veins under resting conditions and simple physiologic maneuvers (PRG) or during a standardized protocol (impedance plethysmography). Measurements of blood volume changes are made with pressure cuffs, strain-gauge meters, or electrical impedance metering. Its accuracy is not as high as that of compression US, and it must be performed with meticulous technique. Also, it does not detect most cases of calf vein thrombosis (sensitivity of 20 to 30%). Consequently, plethysmography-based techniques are now rarely used.

Light rheography (photoplethysmography) is a technique that gives a signal proportional to the blood volume in the subcutaneous tissues. It uses infrared detectors. It performs poorly for the detection of DVT but can be used to confirm the presence of venous insufficiency.

Thermography relies on the detection of temperature changes in the limb to diagnose DVT. It may work well for active superficial thrombophlebitis, but it has limited utility for most cases of DVT. It is unlikely that it will identify most patients with nonobstructive DVT.

Radionuclide Imaging

There are two approaches to the use of radioactive compounds: imaging of the vein lumen, and use of radiopharmaceutical complexes that target thrombi. The vein lumen can be visualized by labeling the blood pool (i.e., erythrocytes) with Technetium-99m. Acute DVT replaces labeled blood and causes a loss of blood pool radioactivity. This causes a defect on the image. This test has an accuracy of close to 90% when large obstructive venous thrombi are present in the femoropopliteal veins. A radionuclide venogram can also be performed during the injection of Tc-99m labeled macroaggregated albumin, typically as part of a pulmonary perfusion scintigram. Nonvisualization of the vein is then used as a diagnostic criterion.

There are many approaches to the use of active uptake of a radiolabeled compound by forming thrombi. Diagnostic tests that rely on this approach include labeled fibrinogen, platelets, fibrin, and plasmin. They perform best for DVT located below the knee or in the lower thigh. Iodine-labeled fibrinogen has long served as a "gold standard" with sensitivity above 80 to 90%, but it is no longer available. Labeled platelets can also be used. Their sensitivity is low for detecting thrombi above the knee: this is due to the small amount of radioactivity that accumulates in the forming thrombus with respect to the amount of background radioactivity. This can be improved by delayed (24-hour) imaging. Uptake is also decreased by concurrent anticoagulation. Labeled antifibrin antibody also suffers from a low signal-to-noise problem that decreases the sensitivity for detecting thrombi above the mid-thigh. Labeled plasmin, as reported in the literature, is very sensitive. Its specificity, however, is poor; the highest reported values for specificity vary between 60 to 70%.

Magnetic Resonance Imaging

Magnetic resonance venography (MRV) has principally been used for evaluating the pelvic veins. Thrombus shows up either as a venous segment without flow or as a discrete filling defect in the vein lumen with a flow-based approach such as time-of-flight or gradient-focused rapid imaging. The accuracy is high for the pelvic veins, and it is also reported to be above 90% in the few series studying its application to the femoro-popliteal system and the calf veins. Contrast enhanced MRI following the intravenous injection of a gadolinium based complex is also principally used in evaluating pelvic veins and is rarely used for the lower extremities. An alternative imaging approach is to use MRI to directly image thrombus while it is forming. Selective pulse sequences that highlight the signal in forming thrombi have shown good diagnostic performance, but diagnostic experience to date has been limited to one group of investigators. Patients with pacemakers or claustrophobia cannot tolerate the procedure. MRV is likely to be used when venous thrombi are located above the inguinal ligament or when extrinsic compression on the iliac veins mimics the signs and symptoms of DVT.

Computed Tomographic Venography

CT can be used to diagnose leg vein DVT. This approach was originally used for imaging of the iliac veins. It is superior to iliac vein venography because it can identify sources of extrinsic compression of the iliac vein as well as diagnose deep vein thrombosis. The technique does not, however, give the fine anatomic detail of the vein lumen and may not show evidence of scarring due to previous episodes of DVT. CT venography in conjunction with CT pulmonary angiography has recently been investigated for its ability to image the thigh and calf veins. Delayed (3 minute) imaging shows good diagnostic performance when compared to contrast venography and ultrasound imaging. One advantage of the approach is the ability to screen for both DVT and pulmonary embolism during a single CT examination. The accuracy and cost-efficacy of this approach have yet to be fully defined.

Plasma D-Dimer Levels

Various blood tests are able to detect elevated levels of plasma D-dimer. This plasma constituent is present when the fibrin from active thrombus is released.

Although very sensitive (above 95%), this test is very nonspecific (less than 50%), since it indicates that thrombus is forming, but not where. It has clinical utility since it has a high sensitivity and the negative predictive value of the test is very high. It is often used as an initial screening test and in conjunction with US imaging and CT pulmonary angiography when findings of these studies are negative despite high clinical suspicion for thromboembolic disease.

Patients with Suspected Pulmonary Embolism

The strong linkage between lower extremity DVT and pulmonary embolism has sometime led to an investigation of the lower extremity veins in patients suspected of having a pulmonary embolism. The diagnostic yield of a positive venous US is low, typically less than 10%, in such patients. More recent data also indicate that the use of follow-up US in patients with negative CT angiography is low.

Summary

The current approach to the evaluation of a symptomatic patient with suspected acute DVT favors venous US. Other imaging approaches are either more invasive (contrast venography), less accurate or less cost-effective for suspected DVT of the femoral or popliteal veins. Suspected involvement of the iliac veins can be investigated with venography or CT. Delayed CT venography following an arm vein injection has shown good reliability as compared to US and venography. MRV is reliable for the pelvic and thigh veins but has yet to be evaluated in any large clinical series for evaluating calf veins. Plasma D-dimer levels are excellent as a screening test in high-risk patients or in the presence of high clinical suspicion, but a positive result must be confirmed by other studies, such as CT or US.

Users of these guidelines must take into consideration the recent recommendation that symptomatic calf vein DVT needs to be treated with systemic anticoagulation.

Abbreviations

- CT, computed tomography
- CTPA, CT pulmonary angiography
- INV, invasive
- IPG, impedance plethysmography
- MAA, macroaggregated albumin
- MRI, magnetic resonance imaging
- NUC, nuclear medicine
- PE, pulmonary embolism
- US, ultrasound

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

Selection of appropriate radiologic imaging procedures for evaluation of patients with suspected lower extremity deep vein thrombosis

Subgroups Most Likely to Benefit

Patients with lower extremity deep vein thrombosis, especially involving the popliteal and above-the-knee veins which are strongly associated with the risk of pulmonary embolism.

POTENTIAL HARMS

Contrast venography carries some risks: contrast reaction, local irritation or skin loss due to extravasation, renal failure, and chemically induced thrombophlebitis.

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.

IMPLEMENTATION TOOLS

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

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Polak JF, Yucel EK, Bettmann MA, Casciani T, Gomes AS, Grollman JH, Holtzman SR, Sacks D, Schoepf J, Stanford W, Jaff M, Moneta GL, Expert Panel on Cardiovascular Imaging. Suspected lower extremity deep vein thrombosis. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 5 p. [44 references]

ADAPTATION

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

DATE RELEASED

1995 (revised 2005)

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

Committee on Appropriateness Criteria, Expert Panel on Cardiovascular Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Joseph F. Polak, MD, MPH; E. Kent Yucel, MD; Michael A. Bettmann, MD; Thomas Casciani, MD; Antoinette S. Gomes, MD; Julius H. Grollman, MD; Stephen R. Holtzman, MD; David Sacks, MD; Joseph Schoepf, MD; William Stanford, MD; Michael Jaff, MD; Gregory L. Moneta, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Needleman L, Polak JF, Bettmann MA, Boxt LM, Gomes AS, Grollman J, Henkin RE, Higgins CB, Kelley MJ, Pagan-Marin H, Stanford W. Suspected lower extremity deep vein thrombosis. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):49-53.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 20, 2001. The information was verified by the guideline developer on March 14, 2001. The summary was updated by ECRI on March 24, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents.

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