Complete Summary

GUIDELINE TITLE

Clinical policy: critical issues in the evaluation and management of adult patients presenting with suspected lower-extremity deep venous thrombosis.

BIBLIOGRAPHIC SOURCE(S)

Clinical policy: critical issues in the evaluation and management of adult patients presenting with suspected lower-extremity deep venous thrombosis. Ann Emerg Med 2003 Jul;42(1):124-35. [108 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Lower-extremity deep venous thrombosis (DVT)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Emergency Medicine
Family Practice
Internal Medicine
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To focus on three major areas of interest and/or controversy:

- Utility of D-dimer testing in the diagnostic evaluation of lower-extremity deep venous thrombosis (DVT)
- Utility of venous Doppler ultrasonography in the diagnostic evaluation of lower-extremity DVT
- Indications for fibrinolytic therapy in DVT

TARGET POPULATION

Adult patients presenting with signs or symptoms of lower-extremity deep venous thrombosis (DVT)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Pretest probability assessment of deep venous thrombosis (DVT) (e.g., scoring system of Wells et al.)
2. Bilateral contrast venography
3. Lower-extremity venous ultrasonography, including serial ultrasonography, when necessary
4. Quantitative D-dimer assay (enzyme-linked immunosorbent assay [ELISA] or turbidimetric assay) or qualitative whole-blood D-dimer assay

Management

Fibrinolytic treatment

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Bleeding and other complications of fibrinolytic treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

An initial MEDLINE search for articles published from January 1995 through April 2001 was performed using the key words deep venous thrombosis and yielded 6,727 hits. The search was therefore limited to clinical trials and clinical policies, which reduced the hits to 675. The abstracts from these articles were reviewed by subcommittee members who then met to select areas of critical importance on which to focus this policy. Pertinent practice guidelines reviewed in the development of this document included the 1996 American Heart Association "Management of Deep Vein Thrombosis and Pulmonary Embolism," the 1998 American College of Chest Physicians consensus statement "Opinions Regarding the Diagnosis and Management of Venous Thromboembolic Disease," 2000 recommendations on antithrombotic therapy from the American College of Chest Physicians Sixth ACCP Consensus Conference on Antithrombotic Therapy, and the 1999 American Thoracic Society "The Diagnostic Approach to Acute Venous Thromboembolism". Subcommittee members also supplied references with direct bearing on the policy by reviewing bibliographies of initially selected papers or from their own knowledge base.

NUMBER OF SOURCE DOCUMENTS

675

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

During the review process, all papers used in the formulation of this policy were classified by the subcommittee members into 3 classes based on design of study, with design 1 representing strongest evidence and design 3 representing weakest evidence for therapeutic, diagnostic, and prognostic clinical reports respectively. Reports were then graded on 6 dimensions thought to be most relevant to the development of a clinical guideline: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures, biases (e.g., selection, detection, transfer), external validity (generalizability), and sufficient sample size. Articles received a final grade (I, II, III) based on a predetermined formula taking into account design and grade of study. Articles with fatal flaws were given an "X" grade and not used in the creation of this policy.

Literature Classification Schema*

Design/Class 1

Therapy[#]: Randomized, controlled trials or meta-analyses of randomized controlled trials

Diagnosis[&]: Prospective cohort using a criterion standard

Prognosis**: Population prospective cohort

Design/Class 2

Therapy[#]: Nonrandomized trial

Diagnosis[&]: Retrospective observational

Prognosis**: Retrospective cohort, case control

Design/Class 3

Therapy[#]: Case series, case report, other (e.g., consensus, review)

Diagnosis[&]: Case series, case report, other (e.g., consensus, review)

Prognosis**: Case series, case report, other (e.g., consensus, review)

*Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

[#]Objective is to measure therapeutic efficacy comparing $\geq$2 interventions.

[&]Objective is to determine the sensitivity and specificity of diagnostic tests.

**Objective is to predict outcome including mortality and morbidity.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

During the review process, all papers used in the formulation of the recommendations in this policy were classified by the subcommittee members into 3 classes based on design of study, with design 1 representing strongest evidence and design 3 representing weakest evidence for therapeutic, diagnostic, and prognostic clinical reports respectively (see Appendix A of the original guideline document). Reports were then graded on 6 dimensions thought to be most relevant to the development of a clinical guideline:

1. Blinded versus nonblinded outcome assessment
2. Blinded or randomized allocation
3. Direct or indirect outcome measures
4. Biases (e.g., selection, detection, transfer)
5. External validity (i.e., generalizability)
6. Sufficient sample size

Articles received a final grade (I, II, III) on the basis of a predetermined formula taking into account design and grade of study (see Appendix B of the original

guideline document). Articles with fatal flaws were given an "X" grade and not used in the creation of this policy.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Clinical findings and strength of recommendations regarding patient management were made according to the following criteria:

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on "strength of evidence class I" or overwhelming evidence from "strength of evidence class II" studies that directly address all the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on "strength of evidence class II" studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of "strength of evidence class III" studies).

Level C recommendations. Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence or, in the absence of any published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Expert review comments were received from individual emergency physicians; members of the American College of Emergency Physicians (ACEP) Section of Emergency Ultrasound; physicians from other specialties, such as cardiologists; and specialty societies, including individual members of the American Academy of Family Physicians, American College of Cardiology, American College of Chest Physicians, American College of Radiology, and the Society of Critical Care Medicine. Their responses were used to further refine and enhance this policy.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of evidence (Design/Class 1-3) and strength of recommendations (Level A-C) are provided at the end of the Major Recommendations.

I. Can lower extremity deep venous thrombosis (DVT) be excluded by a negative D-dimer?

Level A recommendations. None specified.

Level B recommendations. In patients with low clinical probability for lower-extremity DVT, the following test results can be used to exclude DVT:

1. A negative quantitative D-dimer assay result (turbidimetric or enzyme-linked immunosorbent assay [ELISA]) for exclusion of proximal (DVT from the knee to the inguinal ligament) and distal (DVT isolated to the calf) lower-extremity DVT.
2. A negative whole blood D-dimer assay result in conjunction with the Wells et al scoring system for exclusion of proximal and distal DVT.
3. A negative whole blood D-dimer assay result for exclusion of proximal lower-extremity DVT.

   Patients with a moderate-to-high risk of lower-extremity DVT cannot have DVT excluded by a single negative D-dimer test.

Level C recommendations. None specified.

II. Can lower-extremity DVT be excluded by normal findings on a venous ultrasonographic scan?

Level A recommendations. None specified.

Level B recommendations. In patients with low clinical probability for lower-extremity DVT, negative findings on a single venous ultrasonographic scan in symptomatic patients excludes proximal (DVT from the knee to the inguinal ligament) lower-extremity DVT and clinically significant distal (DVT isolated to calf) lower-extremity DVT. In patients with moderate to high

pretest probability of lower-extremity DVT, serial ultrasonographic examinations need to be performed. (Serial venous ultrasonographic examinations refers to scheduling a patient for follow-up ultrasonographic examination within 5 to 7 days or referral of the patient to a primary care physician for follow-up management). Patients with high suspicion of pelvic or inferior vena cava thrombosis may require additional imaging technique.

Level C recommendations. None specified.

III. What are the indications for fibrinolytic therapy in lower-extremity DVT?

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. Consider fibrinolytic therapy in patients with limb-threatening thrombosis of the iliofemoral system in whom the benefits of treatment outweigh the risks of serious bleeding complications.

Definitions:

Strength of Evidence

Literature Classification Schema*

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#Objective is to measure therapeutic efficacy comparing ≥2 interventions.

&Objective is to determine the sensitivity and specificity of diagnostic tests.

**Objective is to predict outcome including mortality and morbidity.

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on "strength of evidence class I" or overwhelming evidence from "strength of evidence class II" studies that directly address all the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on "strength of evidence class II" studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of "strength of evidence class III" studies).

Level C recommendations. Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence or, in the absence of any published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

CLINICAL ALGORITHM(S)

None provided.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

These guideline recommendations can assist clinicians with appropriate and safe evaluation and management of patients presenting to the emergency department (ED) with lower-extremity deep venous thrombosis (DVT).

POTENTIAL HARMS

Contrast Venography

The main drawback to contrast venography is that many radiologists are now uncomfortable, or unwilling, to perform this procedure. The procedure does require injection of contrast and can produce chemical phlebitis.

Fibrinolytic therapy

Increased risk of intracranial hemorrhage and mortality from fibrinolytic therapy

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This policy is not intended to be a complete manual on the initial evaluation and management of patients with deep venous thrombosis (DVT), but rather a focused look at critical issues that have particular relevance to the practice of emergency medicine. Detailed discussion of risk factors, etiology, pathophysiology, physical examination findings, and anticoagulation therapy can be found in any standard textbook of emergency medicine or internal medicine. Some areas considered for discussion but not included in this policy were utilization of low molecular-weight heparin, effectiveness of aspirin in DVT prophylaxis, indications for vena cava filter placement, risk factors for predicting reoccurrence, computed tomography (CT) and magnetic resonance imaging (MRI) venography, nuclear venography, impedance plethysmography, and strain gauge plethysmography. This policy is also nondirective on proposed management algorithms for the evaluation and treatment of patients with suspected DVT, as well as on how to deal with conflicting test results. These areas represent topics that the American College of Emergency Physicians (ACEP) may address in future updates of this current policy.
- This policy presents evidence for answering important questions about these critical diagnostic and management issues. Recommendations in this policy are not intended to represent the only diagnostic and management options that emergency physicians can consider. The American College of Emergency Physicians clearly recognizes the importance of the individual clinician´s judgment. Rather, they define for the clinician those strategies for which medical literature exists to provide strong support for answers to the critical questions addressed in this policy.
- Although this policy focuses exclusively on lower-extremity DVT, it is important to realize that the increased use of indwelling catheters in the subclavian vein (e.g., in chemotherapy patients and dialysis patients), may result in an increased frequency of upper-extremity DVT in the emergency department. Preliminary evidence suggests that pulmonary embolism (PE) resulting from upper-extremity DVT occurs at approximately the same frequency as PE resulting from lower-extremity DVT. There currently is insufficient evidence in the literature for any evidence-based discussion on upper-extremity DVT. It is hoped that future revisions of this policy will be able to address this issue.

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

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2003 Jul

GUIDELINE DEVELOPER(S)

American College of Emergency Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Emergency Physicians

GUIDELINE COMMITTEE

American College of Emergency Physicians (ACEP) Clinical Policies Subcommittee on Suspected Lower-Extremity Deep Venous Thrombosis

ACEP Clinical Policies Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

Clinical policies are scheduled for revision every 3 years; however, interim reviews are conducted when technology or the practice environment changes significantly.

GUIDELINE AVAILABILITY

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

Print copies: Available from the American College of Emergency Physicians, ACEP Customer Service Department, P.O. Box 619911, Dallas, TX 75261-9911, or call toll free: (800) 798-1822, touch 6.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on November 18, 2003. The information was verified by the guideline developer on December 18, 2003.

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