Complete Summary

GUIDELINE TITLE

Outpatient management of uncomplicated deep venous thrombosis.

BIBLIOGRAPHIC SOURCE(S)

Michigan Quality Improvement Consortium. Outpatient management of uncomplicated deep venous thrombosis. Southfield (MI): Michigan Quality Improvement Consortium; 2007 Aug. 1 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Michigan Quality Improvement Consortium. Outpatient management of uncomplicated deep vein thrombosis. Southfield (MI): Michigan Quality Improvement Consortium; 2005 Aug. 1 p.

** 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.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.
- August 16, 2007, Coumadin (Warfarin): Updates to the labeling for Coumadin to include pharmacogenomics information to explain that people's genetic makeup may influence how they respond to the drug.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Uncomplicated acute deep vein thrombosis (DVT)

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Health Plans
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To achieve significant, measurable improvements in the management of uncomplicated deep venous thrombosis through the development and implementation of common evidence-based clinical practice guidelines
- To design concise guidelines that are focused on key management components of uncomplicated deep venous thrombosis to improve outcomes

TARGET POPULATION

Adult patients $\geq$18 years of age with:

- Diagnosis of acute deep vein thrombosis (DVT), confirmed by duplex ultrasonography or venography
- No contraindications to anticoagulation or use of low molecular weight heparin (LMWH)

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Comprehensive history and physical examination
2. Assessment of risk factors and contraindications to anticoagulation therapy
3. Assessment of therapy compliance

Treatment

1. Low molecular weight heparin (LMWH)
2. Warfarin

Management

1. Assessment of therapy using laboratory values (activated partial thromboplastin time [aPTT], prothrombin time/international normalized ratio [PT/INR], complete blood count [CBC] with platelet count), Anticoagulation Monitoring Log, common bleeding sites, signs/symptoms of pulmonary embolism
2. Patient education

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Michigan Quality Improvement Consortium (MQIC) project leader conducts a search of current literature in support of the guideline topic. Computer database searches are used to identify published studies, existing protocols and/or national guidelines on the selected topic developed by organizations such as the American Diabetes Association, American Heart Association, American Academy of Pediatrics, etc. If available, clinical practice guidelines from participating MQIC health plans and Michigan health systems are also used to develop a framework for the new guideline.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

Levels of Evidence for the Most Significant Recommendations

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational studies
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Using information obtained from literature searches and available health plan guidelines on the designated topic, the Michigan Quality Improvement Consortium (MQIC) project leader prepares a draft guideline to be reviewed by the medical directors' committee at one of their scheduled meetings. Priority is given to recommendations with [A] and [B] levels of evidence (see "Rating Scheme for the Strength of the Evidence" field).

The initial draft guideline is reviewed, evaluated, and revised by the committee resulting in draft two of the guideline. Additionally, the Michigan Academy of Family Physicians participates in guideline development at the onset of the process and throughout the guideline development procedure. The MQIC guideline feedback form and draft two of the guideline are distributed to the medical directors, as well as the MQIC measurement and implementation group members, for review and comments. Feedback from members is collected by the MQIC project leader and prepared for review by the medical directors' committee at their next scheduled meeting. The review, evaluation, and revision process with several iterations of the guideline may be repeated over several meetings before consensus is reached on a final draft guideline.

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

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

When consensus is reached on the final draft guideline, the medical directors approve the guideline for external distribution to practitioners with review and comments requested via the Michigan Quality Improvement Consortium (MQIC) health plans (project leader distributes final draft to medical directors' committee, measurement and implementation groups to solicit feedback).

The MQIC project leader also forwards the approved guideline draft to appropriate state medical specialty societies for their input. After all feedback is received from external reviews, it is presented for discussion at the next scheduled committee meeting. Based on feedback, subsequent guideline review, evaluation, and revision may be required prior to final guideline approval.

The MQIC Medical Directors approved this updated guideline in August 2007.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The level of evidence grades (A-D) are provided for the most significant recommendations and are defined at the end of the "Major Recommendations" field.

Initial Assessment

- Perform initial comprehensive history and physical examination; consider conditions predisposing to deep vein thrombosis (DVT).
- Assess risk factors and contraindications to outpatient anticoagulation therapy. (See "Contraindications" field in this summary.)
- Assess patient/caregiver ability and compliance for outpatient therapy and need for homecare resources

Pharmacologic Interventions

- Outpatient therapy is preferred if no contraindications (see "Contraindications" field in this summary)
- Begin warfarin after 1st dose of low molecular weight heparin (LMWH) **[A]**; on same day, titrate to International normalized ratio (INR) range of 2.0 to 3.0.
- Continue LMWH until INR range 2.0 to 3.0 for 2 consecutive days (usually LMWH 5 to 7 days) **[A]**.

- Maintain warfarin therapy at least 3 months in therapeutic INR range **[A]**, longer if risk of recurrence.
- Ask about any changes in diet, medications, and compliance before any dosage adjustment.

Testing/Monitoring

- Obtain baseline lab values: activated partial thromboplastin time (aPTT), prothrombin time (PT)/INR, complete blood count (CBC) with platelet count. Consider platelet count 3 to 5 days into anticoagulation therapy.
- Monitor warfarin therapy using INR; no lab monitoring required for LMWH unless special circumstances such as renal insufficiency or extremes of body weight.
- Frequent INR monitoring is necessary at the onset of therapy (e.g., at least 2 checks in the first week of therapy); then at least 2 to 3 times per week for the next 1 to 2 weeks. When stable, monitor every 4 to 8 weeks.
- Maintain an Anticoagulant Monitoring Log (or dose adjustment system) for each patient treated with warfarin.
- Monitor common bleeding sites: gums, nose, gastrointestinal, genitourinary, and skin.
- Monitor for signs/symptoms of pulmonary embolism, risk factors, and side effects.
- Management through a specialized program for anticoagulation monitoring, if available.

Patient Education

- Inform patient/caregiver of the reasons for and benefits of therapy, potential side effects, importance of follow-up monitoring, warfarin dosage adjustment, compliance, dietary recommendations (i.e., a diet that is constant in vitamin K), the potential for drug interactions, safety precautions, and recognizing internal bleeding.
- Instruct patient/caregiver on symptoms of pulmonary embolism, extension of DVT, and self-injection of LMWH.
- The patient should be encouraged to be ambulatory after an appropriate weight-based dose of LMWH **[D]**.
- Compression stocking should be used routinely to prevent postthrombotic syndrome **[A]**, beginning within 1 month of diagnosis of proximal DVT and continuing for a minimum of 1 year.

Definitions:

Levels of Evidence for the Most Significant Recommendations

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational studies
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is provided for the most significant recommendations (See "Major Recommendations" field).

This guideline is based on several sources, including: Management of Venous Thromboembolism: A Clinical Practice Guideline from the American College of Physicians and the American Academy of Family Physicians. Ann Intern Med. 2007;146:204-10.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Through a collaborative approach to developing and implementing common clinical practice guidelines and performance measures for uncomplicated deep vein thrombosis, Michigan health plans will achieve consistent delivery of evidence-based services and better health outcomes. This approach also will augment the practice environment for physicians by reducing the administrative burdens imposed by compliance with diverse health plan guidelines and associated requirements.

POTENTIAL HARMS

Side effects of anticoagulation therapy

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to Initiating Anticoagulation Therapy in the Outpatient Setting

- Pulmonary embolism
- Extensive iliofemoral thrombus
- Known potential for noncompliance
- Recent surgery/trauma
- Active bleeding
- Severe hypertension (HTN)
- Pregnancy
- Known hypercoagulable state
- Catheter-associated deep vein thrombosis (DVT)
- Renal clearance <30 mL/min or creatinine >2.5 mg/dL
- Thrombocytopenia <100,000
- History of heparin-induced thrombocytopenia
- Childbearing age without contraception

Absolute Contraindications to Warfarin

- Pregnancy

Relative Contraindications to Warfarin

- Dementia
- Certain psychoses

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline lists core management steps. Individual patient considerations and advances in medical science may supersede or modify these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Approved Michigan Quality Improvement Consortium (MQIC) guidelines are disseminated through email, U.S. mail, and websites.

The MQIC project leader prepares approved guidelines for distribution. Portable Document Format (PDF) versions of the guidelines are used for distribution.

The MQIC project leader distributes approved guidelines to MQIC membership via email.

The MQIC project leader submits request to website vendor to post approved guidelines to MQIC website (www.mqic.org).

The MQIC project leader completes a statewide mailing of the comprehensive set of approved guidelines and educational tools annually. The guidelines and tools are distributed in February of each year to physicians in the following medical specialties:

- Family Practice
- General Practice
- Internal Medicine
- Other Specialists for which the guideline is applicable (e.g. endocrinologists, allergists, pediatricians, cardiologists, etc.)

The statewide mailing list is derived from the Blue Cross Blue Shield of Michigan (BCBSM) provider database. Approximately 95% of the state's M.D.'s and 96% of the state's D.O.'s are included in the database.

The MQIC project leader submits request to the National Guideline Clearinghouse (NGC) to post approved guidelines to NGC website (www.guideline.gov).

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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DATE RELEASED

2003 Aug (revised 2007 Aug)

GUIDELINE DEVELOPER(S)

Michigan Quality Improvement Consortium - Professional Association

SOURCE(S) OF FUNDING

Michigan Quality Improvement Consortium

GUIDELINE COMMITTEE

Michigan Quality Improvement Consortium Medical Director's Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Physician representatives from participating Michigan Quality Improvement Consortium health plans, Michigan State Medical Society, Michigan Osteopathic Association, Michigan Association of Health Plans, Michigan Department of Community Health and Michigan Peer Review Organization

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Standard disclosure is requested from all individuals participating in the Michigan Quality Improvement Consortium (MQIC) guideline development process, including those parties who are solicited for guideline feedback (e.g. health plans, medical specialty societies). Additionally, members of the MQIC Medical Directors' Committee are asked to disclose all commercial relationships.

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Michigan Quality Improvement Consortium Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 14, 2004. The information was verified by the guideline developer on July 27, 2004. This NGC summary was updated by ECRI on November 28, 2005. The updated information was verified by the guideline developer on December 19, 2005. This summary was updated by ECRI on March 6, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin sodium). This summary was updated by ECRI Institute on June 22, 2007 following the U.S. Food and Drug Administration (FDA) advisory on heparin sodium injection. This summary was updated by ECRI Institute on September 7, 2007 following the revised U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin). This NGC summary was updated by ECRI Institute on March 5, 2008. The updated information was verified by the guideline developer on March 12, 2008.

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