Complete Summary

GUIDELINE TITLE

Management of venous thromboembolism: a clinical practice guideline from the American College of Physicians and the American Academy of Family Physicians.

BIBLIOGRAPHIC SOURCE(S)

Snow V, Qaseem A, Barry P, Hornbake ER, Rodnick JE, Tobolic T, Ireland B, Segal JB, Bass EB, Weiss KB, Green L, Owens DK, American College of Physicians, American Academy of Family Physicians Panel on Deep Venous. 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 Feb 6;146(3):204-10. [77 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** 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.

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SCOPE

DISEASE/CONDITION(S)

Venous thromboembolism, including:

- Deep venous thrombosis (DVT)
- Pulmonary embolism (PE)

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Pulmonary Medicine
Radiology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations for management of venous thromboembolism (VTE)

TARGET POPULATION

Patients who have been given a diagnosis of pulmonary embolism or lower-extremity deep venous thrombosis (DVT)

INTERVENTIONS AND PRACTICES CONSIDERED

Management and Treatment

1. Low-molecular weight heparin (LMWH)
2. Unfractionated heparin
3. Anticoagulation therapy
4. Outpatient treatment with LMWH (for deep venous thrombosis (DVT) and possibly pulmonary embolism)

Prevention

Compression stockings for prevention of post-thrombotic syndrome

MAJOR OUTCOMES CONSIDERED

- Rate of recurrence of deep venous thrombosis (DVT)/incidence of post-thrombotic syndrome after DVT
- Incidence of pulmonary embolism
- Incidence of minor or major bleeding
- Quality-adjusted life-years
- Cost of care
- Death

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The guideline is based on a systematic review of the evidence as detailed in a comprehensive evidence report published in 2003 and updated in the accompanying background paper by members of the Johns Hopkins University Evidence-based Practice Center (EPC) that prepared the original report. Those papers contain substantial additional detail about the evidence (see the "Availability of Companion Documents" field).

Literature Identification

To identify relevant articles, EPC staff searched literature-indexing systems, including MEDLINE, MICROMEDEX, the Cochrane Controlled Trials Register, and the Cochrane Database of Systematic Reviews, beginning in the 1950s. They also examined reference lists from material identified through the electronic searching and from discussion with experts, and reviewed recent tables of contents of the pertinent journals. For their previous report, EPC staff searched for citations through March 2002. For the current review, the search was extended through June 2006.

The criteria for article selection are listed in **Appendix 1** of the systematic review (see "Availability of Companion Documents" field in this summary). Two team members independently reviewed the titles and abstracts and excluded those that

did not meet the eligibility criteria. For primary literature, the article must have been in English, addressed one of the chosen questions, not involved prevention only, included original human data, and not have been a single-patient case report. For the review of systematic reviews, EPC staff used these criteria but also stipulated that the article have included a systematic review, meta-analysis, or cost-effectiveness analysis. Data published only in abstract form were excluded. Each question had additional eligibility criteria. If both reviewers agreed about eligibility, the article was reviewed.

NUMBER OF SOURCE DOCUMENTS

In the previous review, 64 systematic reviews and 148 primary studies were evaluated. Of these, 16 systematic reviews and 32 primary studies were relevant to their questions about management of venous thromboembolism (VTE). In additional searching, EPC staff identified another 3 systematic reviews and 13 primary studies on the questions that were in the previous review. They also reviewed 515 additional abstracts to identify 46 primary studies on 5 additional questions covered in this review. Seven studies, previously included for question 7 above, were eliminated; they were published before 1995 and were inconsistent in their use of objective tests for diagnosing VTE.

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

Assessing Quality of Evidence*

Study Quality	Regarding Treatment, Prevention, and Screening
Level 1: good quality patient-oriented evidence	Systematic review/meta-analysis or randomized, controlled trial with consistent findings High quality individual randomized, controlled trial† All-or-none study‡
Level 2: limited quality patient-oriented evidence	Systematic review/meta-analysis of lower quality clinical trials or of studies with inconsistent findings Lower quality clinical trial Cohort study Case-control study
Level 3: other evidence	Consensus guidelines; extrapolations from bench research; usual practice; opinion; disease-oriented evidence (intermediate or physiologic outcomes only); or case series for studies of diagnosis, treatment, prevention, or screening

*Based on Strength of Recommendation Taxonomy (SORT) [Ebell MH, Siwek J, Weiss BD, Woolf SH, Susman J, Ewigman B, et al. Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. Am Fam Physician. 2004;69:548-56].

†High-quality randomized, controlled trial: allocation concealed, blinding if possible, intention-to-treat analysis, adequate statistical power, adequate follow-up (>80%)

‡In an all-or-none study, the treatment causes a dramatic change in outcomes, such as antibiotics for meningitis or surgery for appendicitis, which precludes study in a controlled trial

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction

A single reviewer abstracted data, and a co-investigator did a secondary review to verify accuracy. Data was summarized in evidence tables and the quality of the article assessed by using validated instruments, where appropriate.

Two authors graded evidence according to the Strength of Recommendation Taxonomy (SORT) developed by a consortium of editors of U.S. family medicine and primary care journals.

Data Synthesis and Analysis

Risk ratios were pooled across studies about duration of oral anticoagulation and generated CIs around the risk ratios with a random-effects model using the method of DerSimonian and Laird; the estimate of heterogeneity was taken from the Mantel-Haenszel model (Stata 9.0, StataCorp., College Station, Texas). The I^2 statistic was calculated as 100% X (Q – degrees of freedom)/Q, where Q is the measure of heterogeneity. Because the I^2 statistic suggested heterogeneity between trials, we do not report pooled results.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Given the prevalence of this condition and its associated morbidity, the guideline developers reviewed the evidence on optimal treatment of venous thromboembolism (VTE). They sought to summarize the evidence to inform the guidelines developed by the American Academy of Family Physicians and the American College of Physicians for management of patients with VTE. The foundation of this background paper was a previous systematic review of diagnosis and management of VTE and the updated review in the accompanying background paper in the Annals of Internal Medicine. For this guideline, they addressed the following questions: 1) Is Heparin or LMWH safer and more

efficacious for initial treatment of VTE? Is it cost-effective or cost-saving to use LMWH rather than unfractionated heparin for the initial treatment of VTE? 2) Is outpatient treatment of VTE safe and effective compared with inpatient treatment? 3) Are compression stockings efficacious at reducing the incidence of postthrombotic syndrome? 4) What are the optimal therapies for pregnant women with VTE? 5) What is the optimal duration of Vitamin K antagonist therapy for VTE treatment and what is the optimal INR for extended duration therapy? 6) What is the evidence to support use of LMWH in place of a vitamin K antagonist for treatment of VTE? 7) What is the incidence of pulmonary embolism and DVT recurrences after placement of vena cava filters? 8) Does catheter-directed thrombolysis for treatment of DVT reduce recurrence rates and reduce the incidence of postthrombotic syndrome relative to standard anticoagulation?

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Is It Cost-Effective or Cost-Saving to Use Low Molecular Weight Heparin (LMWH) rather than Unfractionated Heparin for Initial Treatment of Venous Thromboembolism (VTE)?

The guideline developers identified 14 studies that used decision analysis methods to address the costs of treatment with LMWH compared with unfractionated heparin, regardless of setting. These were published between 1997 and 2006. As detailed in **Appendix Table 2** in the systematic review (see "Availability of Companion Documents" field), 7 studies were designed as cost-effectiveness studies, 6 were cost-minimization studies, and 1 used a decision model that could not be classified as either. A societal perspective was used in quantifying costs in 3 studies, whereas the other 11 took the perspective of a third-party payer or the provider.

The comparisons fell into 2 categories. Seven of the studies modeled the use of low-molecular weight heparin (LMWH) compared with unfractionated heparin, with all drugs administered in the hospital. The other studies modeled the use of LMWH at home compared with unfractionated heparin in the hospital. The source of the estimates for the costs used in the models varied, with half of the studies using actual costs measured in the setting of a clinical trial. The others used costs obtained from databases maintained by the government or a payer, or used costs abstracted from literature review. Similarly, the rates of events included in the models came from actual data observed in trials or from the literature. For the models, 3 of the studies assumed, on the basis of earlier work, that the rates of recurrent thromboses and adverse events were equivalent for LMWH and unfractionated heparin.

Appendix Table 3 in the systematic review (see "Availability of Companion Documents" field) details the results of these studies. Of the 3 cost-minimization studies that compared inpatient low-molecular-weight heparin treatment to inpatient unfractionated heparin treatment, 1 projected a 57% cost savings with use of nadroparin instead of unfractionated heparin, and 1 projected a 32% savings with dalteparin rather than unfractionated heparin. The other study found

no difference in costs between treatment with enoxaparin and unfractionated heparin, cautioning that these costs were accrued in the setting of a clinical trial; as a result the costs were greater than those that would be seen in usual practice, particularly in the enoxaparin group. One of the 4 cost-effectiveness studies of this comparison found that inpatient tinzaparin was both less costly and more efficacious than unfractionated heparin; similarly, 1 found that inpatient bemiparin dominated unfractionated heparin in the cost-effectiveness analysis. The high-quality cost-effectiveness study by Gould and colleagues modeled the use of enoxaparin and unfractionated heparin in the hospital and found that although enoxaparin treatment is more expensive, it is cost-effective compared with unfractionated heparin because of the gain in quality-adjusted life-years. In a secondary analysis, the authors modeled costs if some of the patients receiving enoxaparin were treated as outpatients. They found that if only 8% of the patients were treated as outpatients, this treatment would be not just cost-effective but even cost-saving. A very similar analysis by Aujesky and colleagues reported comparable findings, with cost savings anticipated if just 8% of patients using LMWH are discharged from the hospital early (within 3 days) or if the daily cost of LMWH is under $51 (in 2005 U.S. dollars).

All of the studies investigating outpatient LMWH compared with inpatient unfractionated heparin found that use of LMWH in outpatients was less costly than hospitalization for unfractionated heparin. The cost-effectiveness study by Estrada and colleagues found that use of LMWH at home for clinically stable patients and in the hospital for unstable patients yielded a 10% cost savings over use of unfractionated heparin in the hospital for all patients. The authors noted that the cost savings were largely due to savings on inpatient costs. Rodger and colleagues similarly found a cost savings of 23% when this comparison was made. The 3 cost-minimization studies found outpatient LMWH to yield a cost savings of 57%, 64%, and 91% compared with inpatient unfractionated heparin.

The cost-effectiveness studies were consistent in suggesting that LMWH is either cost-saving or cost-effective compared with unfractionated heparin.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline was approved by the American College of Physicians Board of Regents on April 4, 2006; and approved by the American Academy of Family Physicians Board of Directors on March 28, 2006.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation 1: *Low-molecular-weight heparin (LMWH) rather than unfractionated heparin should be used whenever possible for the initial inpatient*

treatment of deep venous thrombosis (DVT). Either unfractionated heparin or LMWH is appropriate for the initial treatment of pulmonary embolism.

Consistent evidence demonstrates that LMWH is superior to unfractionated heparin for the initial treatment of DVT, particularly for reducing mortality and reducing the risk for major bleeding during initial therapy. Additional trials are needed to more rigorously examine the efficacy of LMWH for the initial treatment of pulmonary embolism, but systematic reviews of existing trials indicate that LMWH is at least as effective as unfractionated heparin for these patients as well. In addition, trials of unfractionated heparin in pulmonary embolism show that many patients are subtherapeutic or supratherapeutic while receiving unfractionated heparin whereas LMWH is quickly and consistently therapeutic, an important consideration in the treatment of VTE.

Recommendation 2: *Outpatient treatment of DVT, and possibly pulmonary embolism, with LMWH is safe and cost-effective for carefully selected patients, and should be considered if the required support services are in place.*

In trials that compared inpatient and outpatient treatment, the rates of recurrent DVT, major bleeding, and death during follow-up differed only slightly. These studies were conducted among highly selected groups of patients and in clinical systems with the required support services in place. Several studies allowed a brief inpatient admission for stabilization of the patients before randomization to the outpatient group. While some studies enrolled patients with concomitant pulmonary embolism, the majority excluded such patients. Inclusion criteria were strict; most studies excluded patients with previous VTE, thrombophilic conditions, significant comorbid illnesses, pregnant patients, and those unlikely to adhere to outpatient therapy. Therefore, this recommendation cannot be generalized.

Recommendation 3: *Compression stockings should be used routinely to prevent postthrombotic syndrome, beginning within 1 month of diagnosis of proximal DVT and continuing for a minimum of 1 year after diagnosis.*

The evidence demonstrated a marked reduction in the incidence and severity of postthrombotic syndrome among patients wearing compression stockings, either over-the-counter stockings or custom-fit stockings, if use was initiated within 1 month diagnosis of proximal DVT. Most diagnoses of postthrombotic syndrome occurred early, within the first 2 years after DVT.

Recommendation 4: *There is insufficient evidence to make specific recommendations for types of anticoagulation management of VTE in pregnant women.*

During pregnancy, women have a 5-fold increased risk for VTE compared with nonpregnant women. Clinicians should avoid vitamin K antagonists in pregnant women because these drugs cross the placenta and are associated with embryopathy between 6 and 12 weeks' gestation, as well as fetal bleeding (including intracranial hemorrhage) at delivery. Neither LMWH nor unfractionated heparin crosses the placenta, and neither is associated with embryopathy or fetal bleeding.

Recommendation 5: *Anticoagulation should be maintained for 3 to 6 months for VTE secondary to transient risk factors, and for more than 12 months for recurrent VTE. While the appropriate duration of anticoagulation for idiopathic or recurrent VTE is not definitively known, there is evidence of substantial benefit for extended-duration therapy.*

For VTE secondary to transient risk factors, 3 or 6 months of treatment was associated with similar risks for recurrent VTE. In the single study that exclusively enrolled patients presenting with a second episode of VTE, extended-duration (>12 months or indefinite) anticoagulant therapy was associated with fewer recurrences than was termination after 6 months of therapy. For patients with idiopathic VTE (including those with recurrent VTE), extended-duration therapy decreased the relative risk for recurrence by 64% to 95%. Length of therapy in the trials varied widely, from greater than 3 months to 12 months to up to 4 years. The results for extended-duration therapy reflect follow-up only to 4 years; the risk–benefit ratio is not known for longer durations. Clinicians should weigh the benefits, harms, and patient preferences in deciding on the duration of anticoagulation.

Recommendation 6: *LMWH is safe and efficacious for the long-term treatment of VTE in selected patients (and may be preferable for patients with cancer).*

Evidence from high-quality randomized trials supports the use of LMWH as comparable to oral anticoagulation for VTE in selected patients. Low-molecular-weight heparin may be a useful treatment for patients in whom control of the international normalized ratio (INR) is difficult, and may be more efficacious than oral anticoagulants in patients with cancer.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of patients with venous thromboembolism

POTENTIAL HARMS

Complications and adverse events associated with treatment of deep venous thrombosis

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The authors of this article are responsible for its contents, including any clinical or treatment recommendations. No statement in this article should be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

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
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Snow V, Qaseem A, Barry P, Hornbake ER, Rodnick JE, Tobolic T, Ireland B, Segal JB, Bass EB, Weiss KB, Green L, Owens DK, American College of Physicians, American Academy of Family Physicians Panel on Deep Venous. 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 Feb 6;146(3):204-10. [77 references] PubMed

ADAPTATION

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

DATE RELEASED

2007 Feb 6

GUIDELINE DEVELOPER(S)

American College of Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Physicians

GUIDELINE COMMITTEE

Clinical Efficacy and Assessment Subcommittee (CEAS)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Annals of Internal Medicine Web site.

Print copies: Available from Amir Qaseem, MD, PhD, MHA, American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106; E-mail: aqaseem@acponline.org

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Segal JB, Streiff MB, Hofmann LV, Thorton K, Bass EB. Management of venous thromboembolism: a systematic review for a practice guideline. Ann Int Med 2007 Feb;146(3):211-22. Electronic copies: Available from the Annals of Internal Medicine Web site.

  Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

- Ebell MH, Siwek J, Weiss BD, et al. Strength of recommendation taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. Am Fam Physician. 2004;69(3):548-56. Electronic copies: Available from the American Family Physician Web site.

PATIENT RESOURCES

The following is available:

- Treatment of venous thromboembolism: recommendations from the American College of Physicians and the American Academy of Family Physicians. Ann Int Med 2007 Feb;146(3):I-43. Electronic copies: Available from the Annals of Internal Medicine Web site.

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

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NGC STATUS

This NGC summary was completed by ECRI Institute on May 9, 2007. The information was verified by the guideline developer on May 24, 2007. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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