



Complete Summary

GUIDELINE TITLE

Antithrombotic therapy for venous thromboembolic disease. In: Sixth ACCP Consensus Conference on Antithrombotic Therapy.

BIBLIOGRAPHIC SOURCE(S)

Hyers TM, Agnelli G, Hull RD, Morris TA, Samama M, Tapson V, Weg JG. Antithrombotic therapy for venous thromboembolic disease. Chest 2001 Jan; 119(1 Suppl): 176S-193S. [263 references]

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

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SCOPE

DISEASE/CONDITION(S)

Venous thromboembolism, including:

- Deep venous thrombosis
- Pulmonary embolism

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Emergency Medicine
Family Practice

Internal Medicine
Obstetrics and Gynecology
Pulmonary Medicine
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To describe the effectiveness of and make recommendations about antithrombotic agents in the treatment of venous thromboembolism

TARGET POPULATION

Patients with venous thromboembolism, including deep venous thrombosis or pulmonary embolism

INTERVENTIONS AND PRACTICES CONSIDERED

Treatment/Management

1. Pharmacologic Management/Treatment
 - a. Heparin therapy: low molecular weight heparin (dalteparin, enoxaparin, nadroparin, tinzaparin), unfractionated intravenous heparin, or adjusted-dose subcutaneous heparin and heparinoids
 - b. Oral anticoagulant therapy: warfarin; warfarin in combination with heparin or low molecular weight heparin
 - c. Thrombolytic therapy (streptokinase, urokinase, alteplase, reteplase)
2. Nonpharmacologic measures to counteract venous stasis, such as compression stockings and pneumatic compression devices
3. Evaluation procedures or tests to assist with management:
 - a. Laboratory tests (activated partial thromboplastin time, prothrombin time, complete blood count, international normalized ratio, amidolytic anti-Xa assay, plasma heparin levels)
 - b. Echocardiography
 - c. Serial noninvasive studies of the lower extremity for assessment of proximal extension of thrombus
4. Selective placement of an inferior vena caval filter

Note: Treatment of heparin-induced thrombocytopenia is discussed in another NGC Guideline Summary, titled [Heparin and low-molecular-weight heparin: Mechanisms of action, pharmacokinetics, dosing, monitoring, efficacy, and safety](#).

MAJOR OUTCOMES CONSIDERED

- Efficacy of antithrombotic therapy in treating venous thromboembolism
- Adverse effects of therapy, such as bleeding, heparin-induced thrombocytopenia
- Thromboembolic recurrence rates

- Mortality rates
- Cost effectiveness of treatment modalities

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

The participants reviewed information from an exhaustive review of the literature.

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

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) (see "Rating Scheme for the Strength of the Recommendations") and the methodologic quality of the underlying evidence (A, B, C+, or C).

Grades of evidence for antithrombotic agents:

1A

Methodological strength of supporting evidence: randomized controlled trials without important limitations

1B

Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

1C+

Methodological strength of supporting evidence: no randomized controlled trials, but randomized controlled trial results can be unequivocally extrapolated; or, overwhelming evidence from observational studies

1C

Methodological strength of supporting evidence: observation studies

2A

Methodological strength of supporting evidence: randomized controlled trials without important limitations

2B

Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

2C

Methodological strength of supporting evidence: observational studies

* Such situations include randomized controlled trials with lack of blinding, and subjective outcomes, in which the risk of bias in measurement of outcomes is high; and randomized controlled trials with large loss to follow-up.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The strength of any recommendation depends on two factors: the trade-off between benefits and risks, and the strength of the methodology that leads to estimates of the treatment effect. The rating scheme used for this guideline captures these factors. The guideline developers grade the trade-off between benefits and risks in two categories: (1) the trade-off is clear enough that most patients, despite differences in values, would make the same choice; and (2) the trade-off is less clear, and each patient's values will likely lead to different choices.

When randomized trials provide precise estimates suggesting large treatment effects, and risks and costs of therapy are small, treatment for average patients with compatible values and preferences can be confidently recommended.

If the balance between benefits and risks is uncertain, methodologically rigorous studies providing grade A evidence and recommendations may still be weak (grade 2). Uncertainty may come from less precise estimates of benefit, harm, or costs, or from small effect sizes.

There is an independent impact of validity/consistency and the balance of positive and negative impacts of treatment on the strength of recommendations. In situations when there is doubt about the value of the trade-off, any recommendation will be weaker, moving from grade 1 to grade 2.

Grade 1 recommendations can only be made when there are precise estimates of both benefit and harm, and the balance between the two clearly favors recommending or not recommending the intervention for the average patient with compatible values and preferences. Table 2 of the original guideline document summarizes how a number of factors can reduce the strength of a recommendation, moving it from grade 1 to grade 2. Uncertainty about a recommendation to treat may be introduced if the target event that is trying to be prevented is less important (confident recommendations are more likely to be made to prevent death or stroke than asymptomatic deep venous thrombosis); if the magnitude of risk reduction in the overall group is small; if the risk is low in a particular subgroup of patients; if the estimate of the treatment effect, reflected in a wide confidence interval (CI) around the effect, is imprecise; if there is substantial potential harm associated with therapy; or if there is an expectation for a wide divergence in values even among average or typical patients. Higher costs would also lead to weaker recommendations to treat.

The more balanced the trade-off between benefits and risks, the greater the influence of individual patient values in decision making. If they understand the benefits and risks, virtually all patients will take aspirin after myocardial infarction or will comply with prophylaxis to reduce thromboembolism after hip replacement. Thus, one way of thinking about a grade 1 recommendation is that variability in patient values or individual physician values is unlikely to influence treatment choice in average or typical patients.

When the trade-off between benefits and risks is less clear, individual patient values will influence treatment decisions even among patients with average or typical preferences.

Grade 2 recommendations are those in which variation in patient values or individual physician values will often mandate different treatment choices, even among average or typical patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) and the methodologic quality of the underlying evidence (A, B, C+, or C) (see "Rating Scheme for the Strength of the Evidence").

Grades of recommendation for antithrombotic agents:

1A

Clarity of risk/benefit: risk/benefit clear

Implications: strong recommendation; can apply to most circumstances, without reservation

1B

Clarity of risk/benefit: risk/benefit clear

Implications: strong recommendation; likely to apply to most patients

1C+

Clarity of risk/benefit: risk/benefit clear

Implications: strong recommendation; can apply to most patients in most circumstances

1C

Clarity of risk/benefit: risk/benefit clear

Implications: intermediate-strength recommendation; may change when stronger evidence available

2A

Clarity of risk/benefit: risk/benefit unclear

Implications: intermediate strength recommendation; best action may differ, depending on circumstances or patients' societal values

2B

Clarity of risk/benefit: risk/benefit unclear

Implications: weak recommendation; alternative approaches likely to be better for some patients under some circumstances

2C

Clarity of risk/benefit: risk/benefit unclear

Implications: very weak recommendation; other alternatives may be equally reasonable

COST ANALYSIS

Cost-Effectiveness of Anticoagulant Therapy

Cost-effective anticoagulant therapy should arrest thrombosis and prevent recurrent venous thromboembolism (VTE), have a low incidence of bleeding and other complications, and be convenient and inexpensive to administer. An early cost-effectiveness analysis ranked several anticoagulant regimens. These regimens all began with a 10- to 14-day course of intravenous (IV) heparin followed by various long-term regimens. In this analysis, warfarin therapy (international normalized ratio [INR] 2.0 to 3.0) was most cost-effective for long-term anticoagulation in most patients with venous thromboembolism. Adjusted-dose subcutaneous heparin or low-molecular weight (LMW) heparin would be the long-term treatment of choice for pregnant patients and those with hypersensitivity to warfarin, or when laboratory facilities are inadequate to monitor warfarin therapy. In some settings, home monitoring of warfarin therapy might afford additional savings.

More recently, low-molecular weight heparin combined with early initiation of warfarin therapy promises to be the most cost-effective therapy because many patients can be treated without hospitalization or with very short inpatient stays. In many locales, this statement already applies to both inpatient and outpatient treatment. Since the price of low-molecular weight heparins has begun to fall, it is expected that statements favoring cost-effectiveness of these drugs will become even more generalizable.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial guidelines were prepared by the chapter committee (the primary authors) and then reviewed separately by the Committee Co-Chairs and methodology experts and finally by the entire group of Consensus Guideline participants.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Please note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Excerpted by the National Guideline Clearinghouse (NGC):

The grading scheme is defined at the end of the Major Recommendations.

Treatment of Venous Thromboembolism

Effective Regimens

1. The guideline developers recommend that patients with deep venous thrombosis or pulmonary embolism should be treated acutely with low molecular weight heparin, unfractionated intravenous heparin, or adjusted-dose subcutaneous heparin (all grade 1A).
2. When unfractionated heparin is used, the guideline developers recommend that the dose should be sufficient to prolong the activated partial thromboplastin time to a range that corresponds to a plasma heparin level of 0.2 to 0.4 IU/mL by protamine sulfate or 0.3 to 0.6 IU/mL by an amidolytic anti-Xa assay (grade 1C+).
3. In comparison to unfractionated heparin, low molecular weight heparin offers the major benefits of convenient dosing and facilitation of outpatient treatment. Low molecular weight heparin treatment may result in slightly less recurrent venous thromboembolism and may offer a survival benefit in patients with cancer. The guideline developers recommend that clinicians use low molecular weight heparin over unfractionated heparin (grade 2B).

Initial Anticoagulation with Heparin

1. The guideline developers recommend that treatment with heparin or low molecular weight heparin should be continued for at least 5 days and that oral anticoagulation should be overlapped with heparin or low molecular weight heparin for at least 4 to 5 days (grade 1A in comparison with treatment for 10 days).

Remark: For most patients, treatment with warfarin can be started together with heparin or low molecular weight heparin. The heparin product can be discontinued on day 5 or day 6 if the international normalized ratio has been therapeutic for 2 consecutive days.

2. For massive pulmonary embolism or severe iliofemoral thrombosis, the guideline developers recommend a longer period of heparin therapy of approximately 10 days (grade 1C).

Long-term Anticoagulation

1. The guideline developers recommend that oral anticoagulant therapy should be continued for at least 3 months to prolong the prothrombin time to a target INR of 2.5 (range, 2.0 to 3.0). When oral anticoagulation is either contraindicated or inconvenient, a treatment dose of low molecular weight heparin or unfractionated adjusted-dose heparin to prolong the activated partial thromboplastin time to a time that corresponds to a therapeutic plasma heparin level for most of the dosing interval should be used (grade 1A).
2. The guideline developers recommend that patients with reversible or time-limited risk factors should be treated for at least 3 months (grade 1A).
3. The guideline developers recommend that patients with a first episode of idiopathic venous thromboembolism should be treated for at least 6 months (grade 1A).
4. For patients with recurrent idiopathic venous thromboembolism or a continuing risk factor such as cancer, antithrombin deficiency, or anticardiolipin antibody syndrome, the guideline developers recommend treatment for 12 months or longer (grade 1C).

Remark: Duration of therapy continues to be individualized in patients with deficiency of proteins C or S, multiple thrombophilic conditions, homocystinemia, and homozygous factor V Leiden.

5. The guideline developers recommend that symptomatic isolated calf vein thrombosis should be treated with anticoagulation for at least 6 to 12 weeks (grade 1A). If for any reason anticoagulation is not administered, the guideline developers recommend that serial noninvasive studies of the lower extremity should be performed over the next 10 to 14 days to assess for proximal extension of thrombus (grade 1C).

Thrombolytic Therapy

Remark: The use of thrombolytic agents in the treatment of venous thromboembolism continues to be highly individualized, and clinicians should have some latitude in using these agents.

In general, patients with hemodynamically unstable pulmonary embolism or massive iliofemoral thrombosis, who are at low risk to bleed, are the most appropriate candidates.

Inferior Vena Caval Procedures

1. The guideline developers recommend placement of an inferior vena caval filter when there is a contraindication or complication of anticoagulant therapy in an individual with or at high risk for proximal vein thrombosis or pulmonary embolism (grade 1C+). The guideline developers also recommend placement of an inferior vena caval filter for recurrent thromboembolism that occurs despite adequate anticoagulation, for chronic recurrent embolism with pulmonary hypertension, and with the concurrent performance of surgical pulmonary embolectomy or pulmonary thromboendarterectomy (grade 1C).

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) and the methodologic quality of the underlying evidence (A, B, C+, or C).

Definitions:

Grades of recommendations:

1A

Clarity of risk/benefit: risk/benefit clear

Methodological strength of supporting evidence: randomized controlled trials without important limitations

Implications: strong recommendation; can apply to most circumstances, without reservation

1B

Clarity of risk/benefit: risk/benefit clear

Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

Implications: strong recommendation; likely to apply to most patients

1C+

Clarity of risk/benefit: risk/benefit clear

Methodological strength of supporting evidence: no randomized controlled trials, but randomized controlled trial results can be unequivocally extrapolated; or, overwhelming evidence from observational studies

Implications: strong recommendation; can apply to most patients in most circumstances

1C

Clarity of risk/benefit: risk/benefit clear

Methodological strength of supporting evidence: observation studies

Implications: intermediate-strength recommendation; may change when stronger evidence available

2A

Clarity of risk/benefit: risk/benefit unclear

Methodological strength of supporting evidence: randomized controlled trials

without important limitations

Implications: intermediate strength recommendation; best action may differ, depending on circumstances or patients' societal values

2B

Clarity of risk/benefit: risk/benefit unclear

Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

Implications: weak recommendation; alternative approaches likely to be better for some patients under some circumstances

2C

Clarity of risk/benefit: risk/benefit unclear

Methodological strength of supporting evidence: observational studies

Implications: very weak recommendation; other alternatives may be equally reasonable

* Such situations include randomized controlled trials with lack of blinding, and subjective outcomes, in which the risk of bias in measurement of outcomes is high; and randomized controlled trials with large loss to follow-up.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (refer to "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management/treatment of antithrombotic therapy in patients with thromboembolism may improve patient outcomes, while reducing the risk for adverse events, recurrence, and unnecessary cost.

POTENTIAL HARMS

Antithrombotic pharmacotherapy has the potential for adverse side effects, such as bleeding, heparin-induced thrombocytopenia, and hypersensitivity reactions.

CONTRAINDICATIONS

CONTRAINDICATIONS

The following are contraindications to specific agents:

1. Heparin. Severe active bleeding; documented hypersensitivity; heparin-induced thrombocytopenia.
2. Low molecular weight heparins and heparinoids. Severe active bleeding; documented hypersensitivity; heparin-induced thrombocytopenia.
3. Warfarin. Severe active bleeding; pregnancy; documented hypersensitivity.
4. Streptokinase. Active bleeding; recent surgery; stroke; or severe trauma; any hemorrhagic disease; recent streptococcal infection or treatment with streptokinase documented hypersensitivity.
5. Urokinase. Active bleeding; recent surgery; severe trauma; any hemorrhagic disease.
6. Alteplase. Active bleeding; intracranial pathologic condition; recent surgery; severe trauma; and hemorrhagic disease.
7. Reteplase. Active bleeding; intracranial pathologic condition; recent surgery; severe trauma; any hemorrhagic disease.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Interpreting the Recommendations

The authors of these guidelines are offering recommendations that should not be construed as dictates by the readers, including clinicians, third-party payers, institutional review committees, and courts. In general, anything other than a 1A recommendation indicates that the chapter authors acknowledge that other interpretations of the evidence and other clinical policies may be reasonable and appropriate. Even grade 1A recommendations will not apply to all circumstances and all patients. For instance, the guideline developers have been conservative in their considerations of cost, and have seldom downgraded recommendations from 1 to 2 on the basis of expense. As a result, in jurisdictions in which resource constraints are severe, alternative allocations may serve the health of the public far more than some of the interventions that we designate grade 1A. This will likely be true for all less-industrialized countries. However, a weak recommendation (2C) that reduces resource consumption may be more strongly indicated in less-industrialized countries.

Similarly, following grade 1A recommendations will at times not serve the best interests of patients with atypical values or preferences. For instance, consider patients who find anticoagulant therapy extremely aversive, either because it interferes with their lifestyle (prevents participation in contact sports, for instance) or because of the need for monitoring. For such patients, clinicians may reasonably conclude that following some grade 1A recommendations for anticoagulation will be a mistake. The same may be true for patients with particular comorbidities (such as a recent GI bleed or a balance disorder with repeated falls) or other special circumstances (such as very advanced age).

The guideline developers trust that these observations convey their acknowledgment that no guidelines or recommendations can take into account the often compelling idiosyncrasies of individual clinical circumstances. No clinician and no one charged with evaluating the actions of a clinician should attempt to apply their recommendations in a rote or blanket fashion.

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

BIBLIOGRAPHIC SOURCE(S)

Hyers TM, Agnelli G, Hull RD, Morris TA, Samama M, Tapson V, Weg JG. Antithrombotic therapy for venous thromboembolic disease. Chest 2001 Jan; 119(1 Suppl): 176S-193S. [263 references]

ADAPTATION

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

DATE RELEASED

2001 Jan

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

Funding was supplied by DuPont Pharmaceuticals.

GUIDELINE COMMITTEE

American College of Chest Physicians Consensus Panel on Antithrombotic Therapy

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Please note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the [Chest - The Cardiopulmonary and Critical Care Journal Web site](#).

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Sixth ACCP Consensus Conference on Antithrombotic Therapy (2001): quick reference guide for clinicians. Northbrook, IL: ACCP, 2001.

Electronic copies: Available in from the [American College of Chest Physicians Web site](#). (Downloadable files intended for use with Palm OS compatible devices are available.)

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348, or by calling 1 (800) 343-2227.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 30, 2001. The information was verified by the guideline developer on October 17, 2001.

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