Venous thromboembolism: the prevention of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients undergoing orthopaedic surgery and other high-risk surgical procedures

NICE guideline
Draft for consultation, October 2006

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.
Contents

Introduction .................................................................................................................. 3
Patient-centred care .................................................................................................... 4
Key priorities for implementation ............................................................................ 5
1  Guidance ............................................................................................................. 7
   1.1 Assessment of risk and patient advice ...................................................... 7
   1.2 Venous thromboembolism prevention for all surgical specialities Error! Bookmark not defined.
   1.3 Venous thromboembolism prevention specific to type of surgery Error! Bookmark not defined.
2 Notes on the scope of the guidance ..................................................................... 12
   2.1 What the guideline covers ......................................................................... 12
   2.2 What the guideline does not cover .......................................................... 12
3 Implementation in the NHS ............................................................................... 13
4 Research recommendations .................................................................................. 14
5 Other versions of this guideline .......................................................................... 18
   5.1 Full guideline .............................................................................................. 18
   5.2 Quick reference guide ................................................................................ 18
   5.3 Understanding NICE guidance: information for patients and carers 18
6 Related NICE guidance .................................................................................... 19
7 Updating the guideline ....................................................................................... 19
Appendix A: The Guideline Development Group ................................................... 20
Appendix B: The Guideline Review Panel ............................................................... 22
Introduction

Venous thromboembolism (VTE) is the blocking of a blood vessel by a blood clot dislodged from its site of origin. Most thrombi (clots) occur in the deep veins of the legs and this is called deep vein thrombosis (DVT). Dislodged thrombi may travel to the lungs and this is called a pulmonary embolus (PE). Formation is associated with inactivity and high-risk surgical procedures. The risk is particularly high in patients undergoing orthopaedic surgery and lengthy operations.

The condition can lead to sudden death due to PE, or cause long-term morbidity due to chronic venous insufficiency, potentially leading to venous ulceration and development of post-thrombotic syndrome (PTS).

This guideline examines the risk of venous thromboembolism and assesses the evidence for the effectiveness of preventative measures. It provides recommendations on the most clinically and cost-effective measures to prevent venous thromboembolism in surgical patients, whilst considering potential adverse effects of the various preventative options.
Patient-centred care

This guideline offers best practice advice on the prevention of venous thromboembolism in patients undergoing orthopaedic surgery and other high-risk surgical procedures.

Treatment and care should take into account patients' needs and preferences. People undergoing orthopaedic surgery and other high-risk surgical procedures should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines – 'Reference guide to consent for examination or treatment' (2001) (available from www.dh.gov.uk).

From April 2007 healthcare professionals will need to follow a code of practice accompanying the Mental Capacity Act (summary available from www.dca.gov.uk/menincap/bill-summary.htm).

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient’s needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Carers and relatives should have the opportunity to be involved in decisions about the patient’s care and treatment, unless the patient specifically excludes them.

Carers and relatives should also be given the information and support they need.
Key priorities for implementation

- Patients should be assessed to identify individual risk factors that, in addition to the proposed surgery, are known to increase the risk of developing venous thromboembolism. Patient-related risk factors for venous thromboembolism are:
  - a history of venous thromboembolism
  - acquired or inherited thrombophilias
  - cancer
  - chemotherapy agents
  - combined oral contraceptives
  - hormone replacement therapy
  - varicose veins in association with phlebitis or a history of venous thromboembolism
  - obesity
  - immobility
  - prolonged travel before or after surgery
  - age over 60.
- Patients should be given verbal and written information about the risks of venous thromboembolism and the effectiveness of prophylaxis.
- Inpatients having surgery should be offered (class II) graduated compression stockings from the time of admission.
- Patients using graduated compression stockings should be shown how to wear them correctly by appropriately trained staff.
- Intermittent pneumatic compression or foot impulse devices can be used as alternatives or in addition to graduated compression stockings while patients are in hospital.
- Patients at increased risk because of the type of surgery or their individual risk factors should be offered mechanical prophylaxis plus either low molecular weight heparin or fondaparinux.
- Fondaparinux or low molecular weight heparin should be continued for 4 weeks after hip fracture surgery.
• Regional anaesthesia reduces the risk of venous thromboembolism compared to general anaesthesia. Its suitability for a given patient and procedure should be considered in addition to any other planned method of thromboprophylaxis.

• Patients should be encouraged to mobilise as soon as possible after their operation.
1 Guidance

The following guidance is based on the best available evidence. The full guideline (‘Venous thromboembolism: the prevention of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients undergoing orthopaedic surgery and other high-risk surgical procedures’) gives details of the methods and the evidence used to develop the guidance (see section 5 for details).

1.1 Assessment of risk and patient advice

1.1.1 Patients should be assessed to identify individual risk factors that, in addition to the proposed surgery, are known to increase the risk of developing venous thromboembolism. Patient-related risk factors for venous thromboembolism are:

- a history of venous thromboembolism
- acquired or inherited thrombophilias
- cancer
- chemotherapy agents
- combined oral contraceptives
- hormone replacement therapy
- varicose veins in association with phlebitis or a history of venous thromboembolism
- obesity
- immobility
- prolonged travel before or after surgery
- age over 60.

1.1.2 Patients should be given verbal and written information about the risks of venous thromboembolism and the effectiveness of prophylaxis.

1.1.3 Consideration should be given to stopping combined oral contraceptives before elective surgery.
Patients should be informed that the immobility associated with continuous travel of more than 3 hours in the weeks before or after their operation may increase the risk of postoperative venous thromboembolism.

1.2 Venous thromboembolism prevention for all surgical specialities

1.2.1.1 Inpatients having surgery should be offered (class II) graduated compression stockings from the time of admission.

1.2.1.2 Intermittent pneumatic compression or foot impulse devices can be used as alternatives or in addition to graduated compression stockings while patients are in hospital.

1.2.1.3 Patients at increased risk because of the type of surgery or their individual risk factors should be offered mechanical prophylaxis plus either low molecular weight heparin or fondaparinux.

1.2.1.4 Patients using graduated compression stockings should be shown how to wear them correctly by appropriately trained staff.

1.2.1.5 Trained staff should be available to monitor the use of stockings and provide further assistance if they are not being worn correctly.

1.2.1.6 Patients should be encouraged to wear their stockings until they return to their usual level of mobility.

1.2.1.7 Graduated compression stockings should not be offered to patients with established peripheral arterial disease.

1.2.1.8 If used on the ward, intermittent pneumatic compression or foot impulse devices should be worn for as much of the time as is practical while the patient is in bed or sitting in a chair.

1.2.1.9 Vena caval filters should be considered for surgical patients with existing deep vein thrombosis and in whom anticoagulation is contraindicated.
1.2.1.10 The risks and benefits of stopping pre-existing established anticoagulation or antiplatelet therapy before surgery should be considered.

1.2.1.11 Regional anaesthesia reduces the risk of venous thromboembolism compared to general anaesthesia. Its suitability for a given patient and procedure should be considered in addition to any other planned method of thromboprophylaxis.

1.2.1.12 If a neuraxial anaesthetic technique is used, the timing of pharmacological prophylaxis should be carefully planned to minimise the risk of spinal haematoma.

1.2.1.13 Patients having surgery should not be allowed to become dehydrated.

1.2.1.14 Patients should be encouraged to mobilise as soon as possible after their operation.

1.2.1.15 Leg exercises should be encouraged in immobilised patients.

1.3 Venous thromboembolism prevention specific to type of surgery

1.3.1 Elective orthopaedic surgery (spinal surgery considered elsewhere)

1.3.1.1 Patients having major elective orthopaedic surgery should be offered mechanical prophylaxis and either fondaparinux or low molecular weight heparin.

1.3.1.2 Patients having hip replacement surgery with one or more patient-related risk factors for venous thromboembolism should have their drug prophylaxis continued for 4 weeks after their operation.
1.3.2  **Hip fracture surgery**

1.3.2.1 Patients having surgery for hip fracture should be offered mechanical prophylaxis and either fondaparinux or low molecular weight heparin.

1.3.2.2 Fondaparinux or low molecular weight heparin should be continued for 4 weeks after hip fracture surgery.

1.3.3  **General surgery recommendations**

1.3.3.1 Patients having major general surgery should be offered mechanical prophylaxis.

1.3.3.2 Patients having major general surgery with one or more patient-related risk factors for venous thromboembolism should be offered mechanical prophylaxis and either low molecular weight heparin or fondaparinux.

1.3.4  **Gynaecological surgery recommendations**

1.3.4.1 Patients having major gynaecological surgery should be offered mechanical prophylaxis.

1.3.4.2 Patients having major gynaecological surgery with one or more patient-related risk factors for venous thromboembolism should be offered mechanical prophylaxis and low molecular weight heparin.

1.3.5  **Cardiac surgery recommendations**

1.3.5.1 Patients having cardiac surgery should be offered mechanical prophylaxis.

1.3.5.2 Patients having cardiac surgery not otherwise anticoagulated and with one or more patient-related risk factors for venous thromboembolism should be offered mechanical prophylaxis and low molecular weight heparin.
1.3.6 Thoracic surgery recommendations

1.3.6.1 Patients having major thoracic surgery should be offered mechanical prophylaxis.

1.3.6.2 Patients having major thoracic surgery with one or more patient-related risk factors for venous thromboembolism should be offered mechanical prophylaxis and low molecular weight heparin.

1.3.7 Urological surgery recommendations

1.3.7.1 Patients having major urological surgery should be offered mechanical prophylaxis.

1.3.7.2 Patients having major urological surgery with one or more patient-related risk factors for venous thromboembolism should be offered mechanical prophylaxis and low molecular weight heparin.

1.3.8 Neurosurgery (including spinal surgery) recommendations

1.3.8.1 Patients having major neurosurgery should be offered mechanical prophylaxis.

1.3.8.2 Patients having major neurosurgery with one or more patient-related risk factors for venous thromboembolism should be offered mechanical prophylaxis and low molecular weight heparin.

1.3.9 Vascular surgery recommendations

1.3.9.1 Patients having major vascular surgery should be offered mechanical prophylaxis.

1.3.9.2 Patients having major vascular surgery with one or more patient-related risk factors for venous thromboembolism should be offered mechanical prophylaxis and low molecular weight heparin.
2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available from [www.nice.org.uk/page.aspx?o=250362](http://www.nice.org.uk/page.aspx?o=250362)

2.1 What the guideline covers

This guideline covers adults (age 18 and older) undergoing surgical procedures that carry a high risk of venous thromboembolism, including:

- orthopaedic surgery (for example, total hip or knee replacement, surgery for hip fracture)
- major general surgery
- major gynaecological surgery (but not elective or emergency Caesarean)
- urological surgery (including major or open urological procedures)
- neurosurgery
- cardiothoracic surgery
- major peripheral vascular surgery.

2.2 What the guideline does not cover

This guideline does not cover patients under the age of 18.

Additionally this guideline does not cover adult patients who are at a high risk of developing venous thromboembolism but are not undergoing surgery. For example the following circumstances and patients are excluded from the guideline (unless patients are undergoing one of the surgical procedures listed above):

- patients with acute myocardial infarction
- patients who have had an acute stroke
- patients with cancer, including those being treated with chemotherapy
- pregnancy and the puerperium
- use of oral contraceptives and hormone replacement therapy
- long-distance travel.
How this guideline was developed

NICE commissioned the National Collaborating Centre for Acute Care to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).

There is more information in the booklet: ‘The guideline development process: an overview for stakeholders, the public and the NHS’ (second edition, published April 2006), which is available from www.nice.org.uk/guidelinesprocess or by telephoning 0870 1555 455 (quote reference N****).

3 Implementation in the NHS

The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in ‘Standards for better health’, issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/CGXXX).

[\textit{NICE to amend list as needed at time of publication}]

- Slides highlighting key messages for local discussion.
- Costing tools
  - Costing report to estimate the national savings and costs associated with implementation.
  - Costing template to estimate the local costs and savings involved.
- Implementation advice on how to put the guidance into practice and national initiatives which support this locally.
- Audit criteria to monitor local practice.
4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

4.1 Incidence of clinical deep vein thrombosis, confirmed pulmonary embolism, major bleeding, and other postoperative adverse outcomes in modern surgical practice.

What is the relevance of surgical procedure and patient risk factors to incidence of clinical DVT, confirmed PE, major bleeding, and other postoperative adverse outcomes (e.g. myocardial infarction, stroke) in modern surgical practice?

The aim should be to recruit patients undergoing a range of surgical procedures with different levels of expected risk of VTE, ensuring coverage of the common operations currently performed in the NHS.

Baseline evaluation would aim to identify risk factors for VTE and for other adverse outcomes (e.g. bleeding and occlusive vascular events). The study would also record any in-hospital drug treatment and discharge medication. Note, however, that this would be a large observational cohort study and would not be appropriate for determining the effects of treatment, since moderate effects cannot be assessed reliably by such studies.

The control (reference) group will be defined, for each parameter (e.g. age) by a category of patients at low risk of VTE (e.g. age < 30).

Why this is important

The chief difficulty faced when formulating the present guidelines was the absence of accurate estimates of VTE risk in the modern era. Although it was possible to estimate the relative risk reductions associated with particular interventions, it was not possible to estimate their associated absolute benefits. It is possible that (owing to changes in anaesthetic practice and
earlier mobilisation) the modern risks of VTE are much lower than is represented by the available trial evidence. Information on absolute risks of VTE (and other postoperative complications) needs to be obtained in order to assess cost effectiveness reliably.

Information from this study would help surgical teams to provide their patients with accurate information about the balance of benefit and risk associated with particular interventions.

This study could be performed easily if the design elements are kept simple, with one-sided forms that can be completed by junior staff at discharge, and follow-up through mailed questionnaires and tracking of mortality via the Office of National Statistics.

4.2 Timing of administration of low molecular weight heparin

What is the effectiveness of low molecular weight heparin (LMWH) started pre-operatively compared to LMWH started post-operatively in adult patients undergoing high-risk surgical procedures at preventing (objectively diagnosed) DVT or PE? All patients should be screened for the presence of DVT and/or PE.

Secondary outcomes of interest are costs, quality of life, other adverse events e.g. myocardial infarction, stroke, extracranial or intracranial bleeding.

Why this is important

The currently available randomised evidence is too limited to determine whether giving LMWH can be safely delayed until after surgery, or whether it must be given pre-operatively. This venous thromboembolism guideline recommends that LMWH is used for many patients at high risk of venous thrombosis is therefore non-specific about timing, and this is a major gap in the evidence.

Although there may be only small differences in safety and efficacy between these two strategies, a policy of giving LMWH post-operatively might reduce
the time that patients need to be in hospital prior to surgery. It therefore might have major benefits for patients.

As there is uncertainty around this question, it should be possible to find surgeons willing to randomise between these two strategies. The principal practical difficulty with this randomised trial would be the need for a very large sample size (possibly >10,000 patients), since the likely differences in DVT/PE and bleeding rates are small.

### 4.3 Combinations of mechanical prophylaxis

What is the effectiveness of graduated compression stockings and either an intermittent pneumatic compression (IPC) device or a foot pump device compared to graduated compression stockings alone at prevention of (objectively diagnosed) DVT and/or PE in adult patients undergoing surgery at high risk of venous thromboembolism (VTE)? Patients may be at high risk of VTE either due to the procedure (e.g. hip fracture), or because they have risk factors for such disease (e.g. thrombophilia, old age).

All patients should be screened for the presence of DVT and/or PE.

Randomisation would be stratified into two groups: (a) patients in whom pharmacological prophylaxis is contraindicated (e.g. because of an increased risk of bleeding); and (b) patients in whom pharmacological prophylaxis is indicated, but the risk of VTE is very high.

Secondary outcomes would be costs, quality of life, skin problems, myocardial infarction, stroke and other adverse events e.g. bleeding.

**Why this is important**

Only a small number of RCTs have evaluated a combination of mechanical methods. These studies have shown promising results, but have involved small numbers of patients, and the large effect sizes observed in some of these studies suggest bias.
This trial would inform the management of two specific groups of patients in whom the available treatment options are restricted:

- patients at high risk of VTE who cannot have heparin because they are also at increased risk of bleeding
- patients at very high risk of VTE who can be given pharmacological prophylaxis who might benefit from combination mechanical thromboprophylaxis.

This trial would help extend the current NICE recommendations. There may be cost savings if the addition of a second mechanical method results in further prevention of VTE.

The proposed research is feasible but depends on the extent to which surgeons are uncertain about the value of combining two mechanical methods of thromboprophylaxis, because this would determine their willingness to randomise. Prior to any trial this issue would need to be explored in detail, perhaps via a questionnaire.
5 Other versions of this guideline

5.1 Full guideline
The full guideline, ‘Venous thromboembolism: the prevention of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients undergoing orthopaedic surgery and other high-risk surgical procedures’ contains details of the methods and evidence used to develop the guideline. It is published by the National Collaborating Centre for Acute Care, and is available from [NCC website details to be added], our website (www.nice.org.uk/CGXXXfullguideline) and the National Library for Health (www.nlh.nhs.uk). [Note: these details will apply to the published full guideline.]

5.2 Quick reference guide
A quick reference guide for healthcare professionals is also available from www.nice.org/CGXXXquickrefguide

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number NXXXX). [Note: these details will apply when the guideline is published.]

5.3 ‘Understanding NICE guidance’
Information for patients and carers (‘Understanding NICE guidance’) is available from www.nice.org.uk/CGXXXpublicinfo

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number NXXXX). [Note: these details will apply when the guideline is published.]
6 Related NICE guidance

NICE is developing the following guidance (details available from www.nice.org.uk):

- Thrombophilia screening for the diagnosis of individuals at high risk of thrombosis. NICE technology appraisal guidance. (Publication expected January 2008)

- Idaraparinux sodium for the treatment of recurrent thromboembolism. NICE technology appraisal guidance. (Publication date TBC)

- Ximelagatran for the treatment of venous thromboembolism. NICE technology appraisal guidance. (Publication date TBC)

7 Updating the guideline

NICE clinical guidelines are updated as needed so that recommendations take into account important new information. We check for new evidence 2 and 4 years after publication, to decide whether all or part of the guideline should be updated. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.
Appendix A: The Guideline Development Group

Professor Tom Treasure (Chair)
Consultant Thoracic Surgeon, Guys Hospital, London

Mr Nigel Acheson
Consultant Gynaecological Surgeon, Royal Devon & Exeter Hospital

Dr Ricky Autar
Clinical Nurse Consultant, University of Leicester (UHL) Trust

Professor Colin Baigent
Clinical Epidemiologist, Clinical Trials Service Unit (CTSU), Oxford

Mrs Kim Carter
DVT Nurse Specialist, Portsmouth Hospitals NHS Trust, Queen Alexandra Hospital, Portsmouth

Mr Simon Carter
Consultant Orthopaedic Oncologist, Royal Orthopaedic Hospital, Birmingham

Mr David Farrell
Patient Representative

Dr David Goldhill
Consultant Anaesthetist, The Royal National Orthopaedic Hospital, Stanmore

Dr John Luckit
Consultant Haematologist, North Middlesex University Hospital

Mr Robin Offord
Director of Clinical Pharmacy, University College Hospital, London

Mr Adam Thomas
Patient Representative
NCC-AC staff in the Guideline Development Group

Dr Jennifer Hill
Project Manager

Dr Philippa Davies
Research Associate/Project Manager

Mr Enrico De Nigris
Health Economist

Mr Peter B Katz
Information Scientist

Mr Carlos Sharpin
Information Scientist/Research Associate

Mr David Wonderling
Senior Health Economist

Dr Arash Rashidian
Methodological Advisor
Appendix B: The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The Panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

[NICE to add]