BOA BLUE BOOK ON VENOUS THROMBOEMBOLISM, FIRST UNEDITED DRAFT, FEB 2011

The Prevention Of Venous Thromboembolic Disease In Orthopaedic Practice

Preface

Introduction

The patient perspective

British Association for Surgery of the Knee (BASK)

Background

The view of the British Society for Surgery of the Knee (BASK) is that all patients should be risk assessed and, as necessary, reassessed for VTE and given prophylaxis taking into account the balance of risk between thrombosis and bleeding in accordance with NICE guidance. Each department should have a protocol agreed with the local drugs and therapeutics committee and VTE group. The protocol should be evidence based wherever possible. This protocol should be adhered to unless there are good clinical reasons not to do so, which should be documented in the notes. Mechanical prophylaxis is strongly recommended as safe and effective. Pharmacological prophylaxis should be used carefully with the agents recommended by the NICE guidelines. Care should be taken interpreting individual product licenses when creating any protocol, especially when considering duration of treatment, indication and use in combination with other agents (eg injectable followed by an oral agent), and finally all adverse reactions should be reported to the appropriate regulatory bodies. It should be noted that the evidence on the efficacy of some of the pharmacological agents is inconclusive. As a result all protocols may need to be regularly updated in the light of fresh evidence and the evidence needs to be specific to the intervention that is being considered as the efficacy may vary from one procedure to another.

Risk assessment

Except where indicated, the risk assessment for venous thromboembolism and haemorrhage for patients with knee pathology or undergoing knee surgery are the same for all patients.

Risk factors for VTE

Surgical procedure with a total anaesthetic and surgical time of more than 60 minutes
The risk assessment and timing may need to be modified to acknowledge the improvement in VTE risk attributable to neuraxial anaesthesia despite the fact that this can at times extend the total operating room time by a significant margin
Expected significant reduction in mobility which includes bed rest for more than 3 days or knee splintage which significantly restricts range of movement (but not bracing where free knee movement is permitted)
Active cancer or cancer treatment
Age over 60 years
Critical care admission
Dehydration
Known thrombophilia
Obesity (body mass index [BMI] > 30 kg/m^2)
One or more significant medical co morbidity
Personal history or first-degree relative with a history of VTE
Use of hormone replacement therapy (HRT) or oestrogen containing contraceptive therapy (OCP)
Varicose veins with phlebitis
Women who are pregnant or have given birth within the previous 6 weeks

Risk factors for bleeding

Active bleeding (including vascular injury, multiple soft tissue / ligament injuries / knee dislocation, any injury with an increased risk of compartment syndrome and patients requiring blood transfusion)
Acquired bleeding disorders (such as acute liver failure)
Concurrent use of anticoagulants known to increase the risk of bleeding
Lumbar puncture/epidural/spinal anaesthesia expected within the next 12 hours or within the previous 4 hours
Acute stroke
Thrombocytopenia (platelet count <75x10^9/l) - including heparin induced thrombocytopenia (HIT)

Uncontrolled systolic hypertension
Untreated inherited bleeding disorders (such as haemophilia and von Willebrand's disease)

VTE prophylaxis general considerations for patients undergoing elective knee surgery

Pre-operative
Wherever possible avoidable risks should be addressed prior to elective knee surgery. This would include ceasing drugs associated with an increased risk of VTE (eg HRT/OCP) or an increased risk of bleeding (eg antiplatelet drugs), at the same time providing appropriate alternative therapy. Elective surgery should be delayed in some circumstances (eg pregnancy) or avoided where the potential risks outweigh the benefits.
Peri-operative
All patients should be encouraged to remain mobile until the point of surgery, wherever possible being admitted on the day of surgery and walking to the operating theatre reception area. They should be kept adequately hydrated throughout admission. Appropriate mechanical means of prophylaxis should be instituted during anaesthesia/surgery.

Post-operative
All patients should commence walking as soon as possible following surgery, as well as being encouraged to move the knee joint where the pathology or surgery undertaken permits (preferably on the day of surgery). Care should be taken with locally applied means of mechanical prophylaxis (eg TED stockings) where the local skin condition or vascular supply is compromised; these methods should be appropriately applied and avoided if it is not possible to ensure they are being used properly. Pharmacological prophylaxis should be instituted and continued post-operatively based on the department's protocol and continued risk assessment. Its use should cover the period of immobility of the patient, but may be prolonged where bracing is used which significantly restricts knee movement. An appropriate strategy for monitoring for heparin induced thrombocytopenia (HIT) should be developed; although rare this condition can be catastrophic and can go unnoticed when patients are discharged on pharmacological agents shortly following major surgery.

Condition specific considerations
Knee pathology and surgery requiring admission is broadly divided into: arthroscopy, non-arthroplasty open procedures, arthroplasty surgery, and fractures / acute soft tissue injuries around the knee. Specific consideration for these conditions is outlined below.

Arthroscopic knee surgery (including ACL reconstruction)
Risk factors for population undergoing procedure
Very low
Duration of risk
1 week
General considerations
Adequate hydration along with early mobilisation of both the patient and the knee joint will suffice for the majority. If there are additional risk factors (eg previous history of VTE) then pharmacological measures should be considered until the patient is mobile.
Risk factors for use of pharmacological prophylaxis specific to the procedure
Haemarthrosis, which may predispose to infection and arthrofibrosis. The risk is moderate and lasts until sound soft tissue healing is established which should be within 2 weeks.

Non-arthroplasty open knee surgery (such as high tibial osteotomy or open ligament reconstruction)
Risk factors for population undergoing procedure

Low

Duration of risk

The duration of the risk will be until the patient is fully mobile, although may be prolonged if the knee is immobilised.

General considerations

Pharmacological prophylaxis should be considered where there are additional risk factors, or where knee movement is restricted by an externally applied brace (this does not include a brace set with unrestricted knee movement).

Risk factors for use of pharmacological prophylaxis specific to the procedure

Depending on the procedure performed, there may be a risk of bleeding into large soft tissue dissection planes. The risk is moderate to low and lasts up to one week depending on soft tissue healing. For upper tibial osteotomy there is a risk of compartment syndrome, particularly in opening wedge procedures, and care should be exercised using pharmacological prophylaxis.

Knee arthroplasty surgery (including primary total/unicompartmental replacement along with revision surgery)

Risk factors for population undergoing procedure

High

Very high in bilateral single stage procedures

Very low in patients of Asian descent (pharmacological prophylaxis is not routinely given to patients in the Far East)

Duration of risk

2 weeks

General considerations

For this group of patients mechanical and pharmacological prophylaxis should generally be offered. The practice of a formal Enhanced Recovery Programme should be encouraged within all departments undertaking knee arthroplasty. Special consideration should be given to the use of regional anaesthesia, mobilisation of both the patient and the knee joint on the day of surgery and strategies to avoid problems that delay mobilisation (eg blood transfusion, post operative postural hypotension and inappropriate analgesic usage). For patients with additional risk factors (eg previous history of VTE) consideration should be given to the use of appropriate prolonged pharmacological prophylaxis (eg formal anticoagulation). Where the individual risk is very high, consideration should be given for the use of an inferior vena cava filter during the peri-operative period in consultation with the local haematology / vascular departments.

Risk factors for use of pharmacological prophylaxis specific to the procedure

In knee replacement surgery, the use of pharmacological prophylaxis may be associated with increased bleeding. This may cause a haemarthrosis or may affect wound healing, both of which may delay patient mobilisation and thus increase the risk of VTE. Furthermore, haemarthrosis may require surgical drainage and, along with poor wound healing, may predispose to deep infection with its consequences, as well as causing knee stiffness. The risk is high and lasts until wound healing is established which may be up to 2 weeks.

Fractures / periprosthetic fractures / acute soft tissue injuries around the knee (including conservative and operative management)

Risk factors for population undergoing procedure

Very low to very high – depending on structures involved, energy of injury and treatment/rehabilitation instituted as well as concurrent injuries

Duration of risk

The duration of the risk will be until the patient is fully mobile, although may be prolonged if the knee is immobilised.

General considerations

Wherever possible the treatment plan should aim to allow early mobilisation of both the patient and the knee joint. If either is not possible then pharmacological prophylaxis should be considered, especially where there are additional risk factors, or where knee movement is restricted by an externally applied brace (this does not include a brace set with unrestricted knee movement).

Risk factors for use of pharmacological prophylaxis specific to the procedure

Depending on the injury / procedure performed, there may be a risk of bleeding into large soft tissue dissection planes or at the site of a fracture. This risk also arises in the presence of a vascular injury. The risk is moderate and lasts up to two weeks depending on soft tissue healing. For injuries distal to the knee there is a risk of compartment syndrome and care should be exercised using pharmacological prophylaxis. In all of these situations a delay to starting pharmacological prophylaxis should be considered until the risk is reduced.

Literature

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Research questions

- Do mechanical methods of prophylaxis have the same benefits as pharmacological methods?
- Do the benefits of new oral anticoagulants outweigh the risks?
- Does an accelerated rehabilitation / enhanced recovery programme lead to a similar VTE rate as standard therapy plus LMWH, and is this effect maintained following discharge?

British Association of Spinal Surgeons (BASS)

Risk factors for population undergoing spinal surgery:

In spinal surgery the catastrophic long term neurological consequences of extradural bleeding need to be balanced against the risk to life of VTE disease. The patient process should involve the active recording of the clinical decision rather than a passive default position of no treatment.

Extreme
High
Moderate
Low
Very low YES
Thus a routine elective discectomy would be low risk .
Duration of risk
1 day
1 week
1month
Other (specify)
Depends on the duration of the procedure and the delay before mobilisation.

Risk factors for use of PP for spinal surgery

In spinal surgery the catastrophic long term neurological consequences of extradural bleeding need to be balanced against the risk to life of VTE disease. The patient process should involve the active recording of the clinical decision rather than a passive default position of no treatment.
There are the additional risks of poor wound healing, oozing and consequent infection. Poor wound healing may delay mobilisation, which in turn may increase the risk of vte.
Rate as

Extreme YES
High
Moderate
Low
Very low

Duration of risk
1 day
1 week

1month YES
Other (specify)

Literature

Nicol M, Yu S, Craig, N, Wardlaw D. Incidence Of Thromboembolic Complications In Lumbar Spinal Surgery In 1,111 Patients, European Spine Journal. 18(10):1548-52, 2009 Oct

Doug Wardlaw

British Elbow and Shoulder Society (BESS)

The consensus views of the British Elbow and Shoulder Surgery Society (BESS)

GENERAL RECOMMENDATIONS

1. Avoid drugs which interact with pharmacological prophylaxis when used (aspirin, NSAIDs, clopidogrol).
2. Avoid mechanical methods for patients with poor or insensate skin.

LEVEL OF VTE RISK	RECOMMENDED PROPHYLAXIS
Very Low	None
Low	None/mechanical
Moderate	Mechanical
High But outweighed by risk of bleeding	Mechanical and then add Pharmacological Prophylaxis (PP) when bleeding risk diminishes
High	PP
Extreme	PP

GENERAL LIKELIHOOD OF RISK for shoulder and elbow surgery

General Risk Factors	Likelihood for open and major shoulder and elbow surgery	Likelihood for arthroscopic and mini-open shoulder and elbow surgery
Total anaesthetic and surgical time greater than 90 minutes	Medium	Low
Bed rest greater than 3 days or significant reduction in mobility	Low/medium	Low
Acute trauma	Medium/high	Low/medium
Age greater than 60 years	Medium/high	Low/medium
Active malignancy including chemotherapy and radiotherapy	Rare	Rare
Personal history of VTE	Rare	Rare
Inherited thrombophilia	Rare	Rare
Family history of VTE (first degree relative)	Rare	Rare
Obesity BMI >30	Medium	Low
Pre-existing major illness (cardiac respiratory metabolic inflammation acute infection)	Low	Rare
Drug use associated with	Low	Low

risk of VTE (oestrogen containing contraceptive pill hormone replacement therapy tamoxifen)		
Immobility	Low	Rare
Pregnancy Or less than 6 weeks post-partum	Rare	Rare
Dehydration	Rare	Rare
Critical care patient	Rare	Rare

DURATION OF RISK

Length of time pharmacological prophylaxis should be continued for IF INDICATED

PROCEDURE	DURATION OF RISK
Day Case and Arthroscopic Surgery	1 week
Mini-open day case and overnight stay surgery	1 week
Open internal fixation for fracture in under 60 year olds with surgery lasting less than 90 minutes	1 week
Open internal fixation for fracture in over 60 year olds with surgery lasting more than 60 minutes	1 month
Open internal fixation for fracture with surgery lasting more than 90 minutes	1 month
Shoulder and elbow joint replacement	1 month
Revision shoulder and elbow joint replacement	1 month
Tumour surgery	1-2 months

RISK FOR PROCEDURES AND GROUPS OF PROCEDURES (shoulder and elbow)

Procedure	Risk Level
Arthroscopy and day case procedures (eg Elbow removal of loose bodies, tennis elbow release, ulnar nerve release and transposition, Arthroscopic Subacromial decompression, Rotator Cuff Repair Excision Distal Clavicle Excision Calcific Deposit	Very Low
Arthroscopy and mini-open overnight stay procedures (eg Joint stabilisation, Rotator Cuff Repair, Internal Fixation of Fracture Fixation of clavicular fracture including non-union,)	Very Low
Internal fixation of fracture (proximal or distal humerus with moderate/significant comminution/complexity)	Moderate
Joint replacement and revision joint replacement	Moderate
Tumour surgery and arthrodesis	High

Literature

Most significant reviews

Sperling and Cofield (2002) identified 2885 shoulder replacements performed at Mayo clinic over a twenty year period from 1981-2001. Five patients out of 2885 had a non-fatal pulmonary embolus. There were no fatalities. This is an incidence of 0.0017%. *(JBJSA; 2002: 1939-41).*

Lyman et al 2006 examined the records of 328,301 patients undergoing joint replacement surgery. They found that the rate of DVT was 0.5% for shoulders, 1.57% for THR and 2.69% for TKR. They found the rate of PE to be 0.23% for shoulders, 0.42% for THR and 0.44% for TKR. *(Clin Orthop 2006;448:152-6)*

Willis, Warren and Craig in 2009 used Doppler on a consecutive series of 100 patients and found DVTs in 13% of patients undergoing TSR . This compares to a rate of 60% in lower limb arthroplasty. They also report one fatal PE and two non fatal PEs. *(JSES 2009;18:100-16)*

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Expert Opinion and Surveys

In a survey of its members the American Shoulder and Elbow Society found 52 cases of PE after elective shoulder surgery among 152 surgeons who claimed to do 100 cases or more per year. Since those members had been active in shoulder surgery for 10 to 30 years this could be interpreted as an incidence of 52/152000 to 52/456000 cases. Three of 152 members would consider pharmacological DVT prophylaxis in elective surgery. Even where risk factors were identified 50% of surgeons would not prescribe any specific measures.

A survey of the members of the British Elbow and Shoulder Society has shown that surgeons occasionally experience problems with VTE in their upper limb practice. 58% did not use any form of prophylaxis during shoulder surgery. Of those using measures only 7% used Heparin or any of its analogues pre-operatively

A study was presented at BESS where HESS data for TSR (cemented/uncemented/resurfacing) for the period October 2006 to September 2008 was analysed. The number of lower limb deep vein thromboses (DVTs) and pulmonary emboli that occurred between one and 55 days following the procedure were recorded. 2177 TSR were performed over the study period. Incidence of (lower or upper limb) DVT was 0.23% (5 patients) and PE was 0.37% (8).

British Hip Society (BHS)

RISK/BENEFIT PROFILE FOR HIP SURGERY, TO INCLUDE PRIMARY & REVISION THR, PELVIC & PROXIMAL FEMORAL OSTEOTOMIES & OPEN HIP DEBRIDEMENT SURGERY

After the initial risk assessment prior to hip replacement, it is important that repeated risk assessment is undertaken if the patient does not follow the expected recovery course, ie develops an infection, suffers a dislocation or requires more prolonged bed rest for any reason, as this may well change the patient's risk profile.

General risk factors for use of pharmacological prophylaxis (PP)

Use of drugs which interact with pharmacological prophylaxis, such as nsaid's, aspirin, clopidogrel.

General risk factors for the use of mechanical methods

These are poor or insensate skin.

Risk factors for population undergoing procedure:

Previous pelvic or acetabular surgery

Surgery on the hip joint with a total anaesthetic and surgical time > 60 minutes

Active malignancy or cancer therapy including chemotherapy and radiotherapy

Personal history of VTE

Inherited Thrombophilia

First degree relative with a history of VTE

Obesity (BMI>30Kg/m2)

Pre-existing illness: cardiac/respiratory/metabolic/endocrine/inflammatory disorders

Varicose veins with Phlebitis

Drugs known to be associated with VTE e.g. oestrogen containing OCP/HRT/Tamoxifen

Immobility or paralysis of one or more limbs

Critical care admission

Factors reducing risk for the procedures:

Young age

Early mobilisation

Full post-operative weight-bearing

Specific VTE risk for procedures above

Moderate to high

Duration of risk

1 month

Risk factors for use of chemical thromboprophylaxis:

The risks in total hip replacement are of poor wound healing, oozing and consequent infection. Deep infection has devastating consequences, requiring further surgery (often 2 or more further operations), increased mortality risk & long-term patient dissatisfaction with outcome of the surgery. 8% of cases with minor wound infections later become deep.

Poor wound healing / wound ooze is associated with later onset of deep infection and may delay mobilisation, which in turn may increase the risk of VTE.

Duration of Risk

2 weeks

Literature

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Research questions

Over 70,000 hip replacements (THR) were carried out in England and Wales in 2009 (NJR 2009 report) and approximately 7,000 in Scotland (Scottish Arthroplasty Project 2009 report). As many as 44% of these patients are thought to develop Deep Venous Thromboses (DVT) and 3% symptomatic Pulmonary Embolism (PE) after hip replacement surgery (NICE: Venous thromboembolism: reducing the risk – guideline (2010)).

Estimates of the all cause mortality at 3 months range between 0.2 to 1.3%. Even with improved methods of anaesthesia and early mobilisation, the 5th annual report of the national joint register reported the 3 month mortality to be 0.6% for those on low molecular weight heparin (LMWH) and 0.7% for patients on aspirin. This potentially equates to over 30,000 DVTs, 2,300 PEs and 460 deaths every year following hip replacements. These deaths are particular tragic as they are unexpected and frequently occur in fit elderly individuals.

In addition, a silent DVT may be associated with an increased risk of developing post thrombotic syndrome (PTS) and to suffer chronic limb swelling/ulceration with life long morbidity although the inclusion of limb swelling as a diagnostic criterion for PTS in this paper may bias the results. (Wille-Jorgensen P, Jorgensen LN, Crawford M. Asymptomatic postoperative deep vein thrombosis and the development of postthrombotic syndrome. A systematic review and meta-analysis. Thrombosis & Haemostasis 2005, 93(2):236-4121). However the impact of asympomatic DVT specifically in the hip replacement population may have been over-estimated (Cordell-Smith JA, Williams SC, Harper WM, Gregg PJ. Lower limb arthroplasty complicated by deep venous thrombosis. Prevalence and subjective outcome. J Bone Joint Surg Br. 2004 Jan;86(1):99-101).

Both mechanical and pharmaceutical methods are used to try and reduce the incidence of venous thromboembolism (VTE). Recent evidence indicates that the prophylaxis should be extended to cover the first post-operative month. Current guidelines recommend the use of daily injections of LMWH or novel oral anticoagulants (anti-thrombin or anti-factor Xa agents). There is a significant cost to the NHS with these therapies. However there are also substantial costs associated with the treatment of patients with DVTs, PEs or PTS. Pharmaceutical anti-clotting agents can cause unwanted bleeding; rates of major bleeding of 2% have been reported after THR, but higher rates of minor bleeding occur which are less well recorded yet can cause substantial morbidity as they predispose the patient to developing deep infection of the joint replacement and necessitate resource intensive revision joint replacement surgery.

There is therefore an urgent need for a large prospective randomised head to head study to assess which method of prophylaxis has the lowest all cause mortality and is most cost effective The recommended forms of prophylaxis include LMWH given by subcutaneous injection daily or one of the recently licensed novel oral agents which either have an anti-thrombin action (such as dabigatran) or they have an anti-factor Xa action (such as rivaroxiban). It is recommended that a chemical prophylactic agent is given to all patients having hip replacement surgery unless they have a contra-indication. The drugs costs for one patient for prophylaxis range from less than a pound for aspirin to approximately £130 for LMWH excluding the costs of administration of an injection, £130 for dabigatran and £180 for rivaroxiban. The annual bill for 75,000 patients is therefore approximately £12 million pounds per year before any monitoring expenses, nursing or hardware costs for administration of an injection are added in.

A study proposal has been submitted to HTA by the BOA Research Committee. The Null Hypothesis is: Will the incidence of death within 90 days of total hip arthroplasty be lower in patients who receive extended thromboprophylaxis with LMWH to 35 days compared to those taking oral aspirin daily or a novel oral anticoagulant (rivaroxiban or dabigatran) to 35 days following total hip arthroplasty?

RISK BENEFIT PROFILE FOR ARTHROSCOPIC HIP SURGERY

The general risk factors

Surgery with a total anaesthetic and surgical time > 90 minutes

Active malignancy or cancer therapy including chemotherapy and radiotherapy

Personal history of VTE

Inherited Thrombophilia

First degree relative with a history of VTE

Obesity (BMI>30Kg/m2)

Pre-existing illness: cardiac/respiratory/metabolic/endocrine/inflammatory disorders

Varicose veins with Phlebitis

Specific VTE risk for the procedure:

Low

Duration of Risk

1 to 2 weeks

Risk factors for use of Chemical Thromboprophylaxis

Low

British Limb Reconstruction Society (BLRS)

VTE risk assessment British Limb Reconstruction Society

Background

Limb reconstruction involves a very heterogeneous population of patients of all ages with diverse diagnoses, including congenital and post traumatic deformities, acute trauma and malignancy reconstruction. The surgeries are complex, individual and often lengthy. Patients may spend many months in a “frame”. Thus it is all but impossible to give a general view of vte risks. Each patient must be individualised. There is a paucity of scientific evidence upon which to base a rational risk/benefit analysis. Anecdotally, symptomatic vte does occur during the limb reconstruction process.

General risk factors/contraindications for use of pharmacological prophylaxis (PP)

Use of drugs which interact with pharmacological prophylaxis, such as nsaid’s, aspirin, clopidegrol. Percutaneous corticotomy or intramedullary osteotomy has a propensity for bleeding which may be aggravated by use of PP and the associated pain may delay mobilisation increasing the risk of vte. Furthermore, increased bleeding

General risk factors/contraindications for the use of mechanical methods

Poor or insensate skin.

Presence of a frame which precludes garment application

Specific types of surgery

imb reconstruction surgery with or without an external fixator

Risk factors for population undergoing procedure:

Surgical procedure with a total anaesthetic and surgical time of > 90 minutes or > 60 minutes if the surgery involves the pelvis or lower limb

Anticipated bed rest greater than 3 days/significant reduction in mobility

Acute trauma

Age>60yrs

Active malignancy or cancer therapy including chemotherapy and radiotherapy

Personal history of VTE

Inherited Thrombophilia

First degree relative with a history of VTE

Obesity (BMI>30Kg/m2)

Pre-existing illness: cardiac/respiratory/metabolic/endocrine/inflammatory disorders/acute infection

Drugs known to be associated with VTE e.g. oestrogen containing OCP/HRT/Tamoxifen

Varicose veins with Phlebitis

Immobility or paralysis of one or more limbs

Pregnancy or ≤6 weeks post partum (Please discuss with obstetric registrar on call)

Dehydration

Critical care admission

Risk factors for population undergoing procedure:

Limb reconstruction surgery which involves bone division is likely to generate a high of vte for up to 1 week following surgery. The majority of patients would be mobile very early after surgery and their mobility would rapidly exceed the pre surgery level. The presence of the external scaffold is probably associated with a low risk of vte for the duration of frame application.

Risk factors for use of PP specific to the procedure

The risks are of excessive bleeding causing pain and possible compartment syndrome. The risk is high and lasts one week. After this, use of PP may predispose to pin site infection. This risk is low and lasts for the duration of the frame application. The effect of PP on bone distraction is unknown. Theoretically, PP may cause a haematoma in the regenerate which might cause cyst formation with failure of regenerate. These considerations would suggest that PP is slightly contraindicated in patients with an external fixator in situ or during the process of distraction osteogenesis.

Literature

There is no available literature

Research questions

What is the risk of significant vte in a patient with an external fixator.

British Orthopaedic Foot and Ankle Society (BOFAS)

A risk Benefit Profile of VTE in foot and ankle Surgery

Prepared by the Scientific Committee of the British Orthopaedic Foot and Ankle Surgery Society

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Introduction:

A survey of the members of BOFAS in May 2010 to establish current opinion on VTE prophylaxis in elective foot and ankle surgery has been undertaken. The respondents to the survey reported undertaking 33,500 elective foot and ankle cases per annum. This is the largest study of this kind. The majority of surgeons (58%) estimated the incidence of symptomatic DVT to be less than 1% in mixed cases including forefoot and hindfoot surgery. Fifty nine per cent of surgeons considered the PE rate to be less than 0.2%, and 91% considered the fatal PE rate to be less than 0.2%.

When asked to specifically estimate the incidence of VTE in their practice the DVT rate was 0.6%, PE rate 0.1% and fatal PE rate of 0.02%. Thus in this mixed group of foot and ankle patients, some of whom received chemoprophylaxis, the estimated death rate from VTE was 1:5000. This compares to the estimated death rate of Heparin Induced Thrombocytopaeina of 1:2000. It should be noted that the oral agents are not currently licensed for use in foot and ankle practice.

BOFAS Statement:

A consensus statement regarding the risk of VTE in foot and ankle surgery was published by BOFAS in March 2008. This statement makes the following points:

Procedure specific factors

All foot and ankle procedures are considered low risk. As such the need for VTE chemoprophylaxis should be determined by patient specific factors.

Prolonged immobilisation

There is little evidence to show that prolonged immobilisation, in a below knee plaster or splint, in the absence of patient related risk factors merits the use of VTE chemoprophylaxis.

We would support the following General Measures:

Pre-operatively discuss the risk of VTE with the patient. The patient should participate in the decision making process.

Minimise the tourniquet time.

Offer all surgical inpatients thigh-length graduated compression/anti-embolism stockings, unless contraindicated (for example, in patients with established peripheral arterial disease or diabetic neuropathy). If thigh-length stockings are not appropriate (for reasons of fit or compliance) knee-length stockings may be used instead.

Advise patients to consider stopping combined oral contraceptives 4 weeks before elective surgery.

Advise patients that hormone replacement therapy is a risk factor for VTED but that it is not necessary to stop before elective surgery provided appropriate thromboprophylaxis is used.

Inform patients that immobility associated with continuous travel of more than 3 hours in the 4 weeks before or after surgery may increase the risk of VTE.

In view of the results of the recent BOFAS survey we see no reason to alter our statement of March 2008. As such forefoot, midfoot and hindfoot surgery are all low risk procedures. Thus this advice covers all areas of foot and ankle surgery. As immobility/ cast immobilisation is an integral part of many procedures, it will not be reviewed as a separate risk factor.

General risk factors for use of pharmacological prophylaxis (PP)

Use of drugs that interact with pharmacological prophylaxis, such as NSAID's, aspirin, clopidogrel.

General risk factors for the use of mechanical methods

Poor or insensate skin

Peripheral vascular disease

Risk factors for population undergoing procedure:

Active malignancy or cancer therapy including chemotherapy and radiotherapy

Personal history of VTE

Inherited Thrombophilia

First degree relative with a history of VTE

Obesity (BMI>30Kg/m2)

Pre-existing illness: cardiac/respiratory/metabolic/endocrine/inflammatory disorders

Varicose veins with Phlebitis

The duration of risk is the duration of immobilisation in a cast, if a cast has been utilized. Post-operative shoes do not constitute a risk factor. It may be that non-weightbearing patients are at higher risk than weightbearing patients

Risk factors for use of PP specific to the procedure

The risks in foot and ankle surgery are of haematoma formation, poor wound healing, oozing and consequent infection. Poor wound healing may delay mobilisation, which in turn may increase the risk of VTE.

The risk of these complications is moderate, apart from ankle arthroplasty, where this risk is high. The risk of bleeding is principally during the first fortnight, before the wound has healed.

Literature

When considering thromboprophylaxis in patients undergoing elective foot and ankle surgery there are some fundamental questions that need to be answered. The incidence of VTE in this patient group has been described as varying between 0.22% and 4%. This is universally accepted as being very low and the consensus among foot and ankle surgeons is that thromboprophylaxis is not proven to be of benefit in this patient group. What is also clear from the literature is that there are specific risk factors that increase the likelihood of VTE developing. These include the routine conditions that increase coagulability. More specific risk factors associated with elective foot and ankle surgery include past history of VTE, hindfoot surgery with immobilisation, non weight bearing while immobilised, age over 60 and obesity (BMI>30). In those patients with 2 or more of these risk factors the VTE incidence was significantly greater.

Forefoot surgery has been shown to have a VTE incidence of between 4 and 0% by Simon and Radl respectively. As such the VTE risk for forefoot surgery, with or without a tourniquet, is not considered high enough to merit chemical prophylaxis. Solis found that the risk of VTE was significantly higher with hindfoot surgery, although the overall incidence was still only 3.5%.

Solis showed increasing tourniquet time to be associated with an increased risk of VTE. On the other hand Wukich and Simon did not demonstrate any increase in VTE incidence with the use of a tourniquet and surprisingly the VTE incidence was greater in patients where calf and ankle tourniquets were used. In both these studies there were no DVT's in patients on

whom thigh tourniquets were used. As such the evidence for using VTE chemoprophylaxis simply as a result of using a tourniquet is insufficient.

The available evidence in the literature appears to be strong enough to support the use of thromboprophylaxis in high-risk patients. Selection is dependent on the patient's own risk level, as opposed to that of the surgery per se.

Radl,R., Kastner,N., Aigner,C., Portugaller,H., Schreyer,H., and Windhager,R.: Venous thrombosis after hallux valgus surgery. J Bone Joint Surg Am, 85-A:1204-1208, 2003.

Simon,M.A., Mass,D.P., Zarins,C.K., Bidani,N., Gudas,C.J., and Metz,C.E.: The effect of a thigh tourniquet on the incidence of deep venous thrombosis after operations on the fore part of the foot. J Bone Joint Surg Am, 64:188-191, 1982.

Solis,G. and Saxby,T.: Incidence of DVT following surgery of the foot and ankle. Foot Ankle Int, 23:411-414, 2002.

Wukich,D.K. and Waters,D.H.: Thromboembolism following foot and ankle surgery: a case series and literature review. J Foot Ankle Surg, 47:243-249, 2008.

Research questions

Level 1 multi-center studies on foot and ankle surgery to provide evidence based guidelines for VTE prophylaxis are required. Colwell performed a meta-analysis of 31 randomised trials investigating the benefits of various chemical and mechanical agents for VTE prophylaxis and was unable to draw any conclusions due to flaws in the studies. It is this deficiency of evidence that needs to be addressed.

Colwell,C.W.: Evidence-based guidelines for venous thromboembolism prophylaxis in orthopedic surgery. Orthopedics, 30:129-135, 2007.

British Orthopaedic Oncology Society (BOOS)

Background

Orthopaedic oncological surgery involves a wide spectrum of disease and site in a heterogeneous patient population. These range from a child undergoing a simple biopsy of an upper limb mass which is not malignant to an elderly person undergoing major reconstructive surgery for a pathological fracture. Surgeries may be associated with significant blood loss and may leave extensive dissected areas with a great propensity for secondary bleeding.

Thus the vte risk benefit profile of prophylaxis will need to be individualised for each patient.

The evidence concerning vte from the literature is sparse. There are case reports of sarcomas arising from veins (usually the IVC), which may cause emboli but whether this particular form of embolism would be prevented by thromboprophylaxis is unknown[1-12]. Two papers suggest that patients with tumours in the thigh are particularly at risk [13, 14].

A few retrospective reviews have documented vte in oncological patients. Mitchell et al reviewed 252 patients, finding a DVT rate of 4%, a PE rate of 1.2%, a fatal PE in 0.4% [13]. All vte's occurred in patients with hip or thigh pathology and the vte often predated definitive surgery

Nathan et al reviewed 87 cases of hip replacement for oncological reasons finding 4 cases of proximal dvt despite prophylaxis with intermittent compression pumps and lmwh. A tumour in the pelvis was associated with increased risk both of vte and wound complications.[15]

Athale et al reported on 70 children (age <= 18 years) undergoing treatment for sarcoma. Clinically significant thromboembolic events occurred in 10 patients. These cases were related to medical treatment of the disease (eg central venous line thrombosis) rather than surgery [17].

Paz-Priele et al studied 122 children with sarcoma finding 19 with clinically significant vte. Once again the vte related to disease or medical treatment rather than to surgery [16].

It is therefore important to separate the vte risk associated with surgery from that associated with the overall disease process and treatment.

A survey of all members of BOOS was carried out to establish a consensus view of the vte risk associated with surgery. One centre has unpublished data showing a low rate of vte. The general consensus was that clinically significant vte is rare except in patients with pathological fracture, who may be bed bound for a period prior to surgery. In these

patietnts, vte might be more associated with immobilisation prior to surgery rather than the surgery itself. Only one centre routinely used pp. There was general concern at the risk of bleeding associated with pp, for which reason there was a preference for intermittent compression garments.

General risk factors for use of pharmacological prophylaxis (PP)

Use of drugs which interact with pharmacological prophylaxis, such as nsaid's, aspirin, clopidegrol.

General risk factors for the use of mechanical methods

These are poor or insensate skin.

Specific risk of vte

Risk factors for population undergoing procedure:

Surgical procedure with a total anaesthetic and surgical time of > 90 minutes or > 60 minutes if the surgery involves the pelvis or lower limb
Anticipated bed rest greater than 3 days/significant reduction in mobility
Acute surgical admission with Inflammatory intra abdominal condition or trauma
Age>60yrs
Active malignancy or cancer therapy including chemotherapy and radiotherapy
Personal history of VTE
Inherited Thrombophilia
First degree relative with a history of VTE
Obesity (BMI>30Kg/m2)
Pre-existing illness: cardiac/respiratory/metabolic/endocrine/inflammatory disorders/acute infection
Drugs known to be associated with VTE e.g. oestrogen containing OCP/HRT/Tamoxifen
Varicose veins with Phlebitis
Immobility or paralysis of one or more limbs
Pregnancy or ≤6 weeks post partum (Please discuss with obstetric registrar on call)
Dehydration
Critical care admission
Risk factors for population undergoing procedure:

Low risk

Patients with upper extremity tumours

Duration of risk

Unknown, probably less than a week

Intermediate risk

All other patients

Duration of risk

Unknown, probably less than a week

High risk

Patients with pathological fractures

Patients with deep tumours of the thigh or pelvis close to or involving vascular structures

Patients with tumours arising from major vessels

Duration of risk
This will vary with the intercurrent illness and treatment. By analogy with total hip replacement in other circumstances, it may be one month
Risk factors for use of PP specific to the procedure

The risk is of bleeding form extensive dissected areas. The risk will depend on the exact surgery undertaken and may be moderate to extreme. The duration of risk is until sound wound healing is established.

References

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British Orthopaedic Sports Trauma & Arthroscopy Association (BOSTAA)

This society considers that the issues with respect to venous thromboembolism in patients under the care of its society members are adequately covered by the recommendations of other specialist societies.

British Scoliosis Society (BSS)

This society considers that the issues with respect to venous thromboembolism in patients under the care of its society members are adequately covered by the recommendations of other specialist societies.

British Society for Children's Orthopaedic Surgery (BSCOS)

The risk of vte in children is generally very low. Routine thromboprophylaxis is not indicated. In an individual patient with thrombophilia or other extraordinary risk factor there may be a need for thrombprophylaxis. Adolescent girls taking the oral contraceptive pill may require thromboprophylaxis.

British Society for Surgery of the Hand (BSSH)

Subject to approval of Membership and Council at BSSH Meeting November 2010

There are very few reported cases of venous thrombosis or pulmonary embolism in Hand Surgery. There is a small risk after major elbow surgery. Two other groups of procedures may carry a theoretical risk of VTE

- prolonged surgery time (brachial plexus reconstruction, major peripheral nerve reconstruction, tumour surgery, replantation)
- ancillary lower limb procedures (fibular flap, nerve or tendon harvest, bone graft)

Universal thromboprophylaxis cannot be justified on either a cost-benefit or risk-benefit basis.

The risks of chemical thromboprophylaxis are likely to be higher after certain procedures especially skin grafts or flaps (flap loss), widespread soft tissue trauma or surgical dissection (compartment syndrome), bone grafting (Haemorrhage).

The NICE Guidelines 2010 suggest the following:

Do not routinely offer VTE prophylaxis

Perform a risk assessment on admission

If increased risk offer mechanical methods and LMWH

Continue prophylaxis until sufficiently mobile

NICE risk factors are:

- Procedure time >90 minutes (>60 minutes for lower limb)
- Active cancer or cancer treatment
- Known thrombophilias
- Obesity (BMI > 30 kg/m2)
- Personal history or first-degree relative with a history of VTE
- Use of HRT
- Use of oestrogen-containing contraceptive therapy
- Varicose veins with phlebitis

The provisional BSSH recommendations in Hand Surgery, which are NICE compliant and properly balanced:

Upper limb procedure lasting more than 90 minutes

- use mechanical compression devices in the operating room and until discharged and fully mobile

Ancillary lower limb procedure >60 minutes

-use mechanical compression devices in the operating room and until discharged and fully mobile

Additional risk factors <90 minutes

- use mechanical compression devices in the operating room and until discharged and fully mobile

Additional risk factors and procedure > 90 minutes (60 minutes for ancillary lower limb)

- consider LMWH started 6 to 12 hours post-operatively until fully mobile (but beware alternative risk of bleeding in some procedures Carefully document the balanced decision for individual patient . Patient may need to continue LMWH after discharge from hospital)

David Warwick August 2010

British Trauma Society (BTS)

(Nothing received....I continue to badger them and have sent a suggestion)

Fractured neck of femur

Background

This document applies to the population suffering osteoporotic fractured neck of femur. Where a fractured neck of femur occurs in a younger person, the information in the trauma or hip society documents would apply.

Older patients who suffer fracture neck of femur are often frail and vulnerable and have multiple medical co-morbidities. Prior to the fracture, many were already relatively immobile and the fracture may immobilise them for a further period.

These patients therefore have a high relative risk of thromboembolism, but in spite of this the clinical impact of deep vein thrombosis (DVT) and pulmonary embolism (PE) is not readily apparent:

- Routine venographic surveillance in the context of trials of thromboprophylaxis has identified deep vein thrombosis in a third to a half of patients recovering from hip fracture - but clinically apparent DVT is a relatively uncommon finding on orthopaedic wards.
- The absolute risk of pulmonary embolism remains only a minor contribution to the very high mortality figures seen during the months after hip fracture – within overall inpatient mortality figures of 10-15%, perhaps 1% of deaths relate to PE.

Skin will often be of poor quality which may contraindicate mechanical prophylaxis and compression stockings may cause ulceration. Use of pharmacological prophylaxis may predispose to haematoma and infection which carries a high morbidity, mortality and economic impact.

These considerations imply that prophylaxis will need to be tailored to the needs of individual patients.

<u>General reasons for additional caution in use of pharmacological prophylaxis (PP)</u>

- *Currently receiving therapeutic anticoagulation*
- *Uncontrolled systolic hypertension > 180mmHg*
- *Severe liver disease or known bleeding disorder*
- *Thrombocytopenia: platelet count < 70 x 109/l*
- *Renal impairment with eGFR < 30ml/min*

- *Lumbar puncture/epidural/spinal anaesthesia within past 4 hours or expected in next 12 hours*
- *Risk of central nervous system bleed e.g. new-onset stroke, head injury or previous subarachnoid haemorrhage*
- *Previous heparin induced thrombocytopenia or heparin allergy*

Specific orthopaedic reasons for initial caution with pharmacological prophylaxis

Which might justify initial delay in starting chemoprophylaxis until patient more fully assessed, associated bleeding addressed, or post-operative haemostasis achieved.

- *Poly-trauma*
- *Potentially unstable spinal pathology*
- *Multipart or unstable pelvic fracture*
- *Subtrochanteric or multipart trochanteric hip fracture*
- *Pagetic hip fracture*

General risk factors for the use of mechanical methods

- *Peripheral neuropathy*
- *Severe peripheral oedema*
- *Arterial insufficiency (suspected or proven): absent or weak foot pulses, a history of intermittent claudication, slow capillary filling*
- *Skin condition concerns: skin infections, leg, foot or pressure ulcer, 'tissue paper' skin or trophic changes,recent skin graft*
- *Known allergy to material of manufacture*

FOR EACH PROCEDURE OR GROUP OF PROCEDURES

Risk factors for population undergoing procedure:

The suggested general risk factor for VTE quoted by NICE are:

- *Total anaesthetic and surgical time of > 60 minutes*
- *Anticipated bed rest greater than 3 days/significant reduction in mobility*
- *Active malignancy or cancer therapy including chemotherapy and radiotherapy*
- *Personal history of VTE*

- *Inherited Thrombophilia*
- *First degree relative with a history of VTE*
- *Obesity (BMI>30Kg/m2)*
- *Pre-existing illness: cardiac/respiratory/metabolic/endocrine/inflammatory disorders/acute infection*
- *Drugs known to be associated with VTE e.g. oestrogen containing OCP/HRT/Tamoxifen*
- *Varicose veins with Phlebitis*
- *Immobility or paralysis of one or more limbs*
- *Dehydration*
- *Critical care admission*

However, nearly all of the population presenting with hip fracture have a combination of risk factors that might be viewed as justification for both chemical and mechanical prophylaxis:

Age >60 and immobilisation or operation (or both) would be anticipated in nearly all patients

As combined prophylaxis is therefore the default position for patients with hip fracture, consideration of other risk factors for VTE may appear redundant. However, attention should still be paid to specific risk factors that might alter management – in particular to the coexistence of factors that might justify consideration of more intensive approaches, such as extended use of fondaparinux, or even full anticoagulation in the post-operative period:

- *Active malignancy or cancer therapy including chemotherapy and radiotherapy*
- *Personal history of VTE*
- *Inherited Thrombophilia*
- *First degree relative with a history of VTE*

Risk factors for population undergoing procedure:

High
Duration of risk
UP to 1 month, until the patient has returned to full mobility
Risk factors for use of PP specific to the procedure

The risks are of poor wound healing, oozing and consequent infection. Poor wound healing may delay mobilisation, which in turn may increase the risk of vte. The risk is high and lasts until wound healing is established.

Rheumatoid Arthritis Surgical Society (RASS)

This society considers that the issues with respect to venous thromboembolism in patients under the care of its society members are adequately covered by the recommendations of other specialist societies.