

Health and Social Care Committee
One-day inquiry into venous thrombo-embolism prevention
VTE 16 – Welsh Orthopaedic Society

Welsh Assembly Health and Social Care Committee one-day inquiry:
Venous Thromboembolism prevention in hospitalised patients in
Wales

Submission from the Welsh Orthopaedic Society

There are two groups of patients under Orthopaedic care; those who have suffered a traumatic injury admitted for the management of bone and soft tissue damage, and those admitted for elective Orthopaedic surgery such as joint replacement.

Venous Thrombosis happens when there is an imbalance in the normal homeostatic mechanisms as a result of blood flow stasis, vessel wall damage and / or activation of the clotting cascade of the patient as a result of injury, surgery or systemic disease.

The incidence of symptomatic Pulmonary Embolus has been shown to be very low in recent series of major elective joint replacement patients^{1,2,3}. The incidence of fatal pulmonary embolus is of the order of 0.07%¹ using aspirin as thromboprophylaxis.

Historical data regarding rates of DVT in Orthopaedic patients are of limited applicability to current practice as peri-operative protocols have changed dramatically with regard to early mobilisation of patients following hip and knee replacement, care with maintaining hydration and use of mechanical calf pumps intra-operatively.

Published rates of DVT in Orthopaedic patients are often based on soft end-points such as venographically or ultrasound detected thrombosis in patients who have no symptoms. Patients who have an asymptomatic DVT may not have any long term adverse consequences as patients who underwent major joint replacement in the 1980s and early 1990s (when prolonged bed rest was common) do not have higher rates of venous ulceration in later life than the population averages^{4,5}. The significance of a diagnosis of asymptomatic DVT is unknown and treatment in this situation may be unnecessary and potentially even harmful.

Trauma patients have two contradictory conditions with regard to thrombo-embolism as they are often immobilised resulting in blood flow stasis and risk of clot formation but they also have an injury which will predispose to bleeding from damaged soft tissues and broken bones.

In the immediate post-operative period all Orthopaedic and Trauma patients have surgical wounds which can bleed. This can result either in external blood loss requiring replacement or more likely internal bleeding that can result in haematoma formation. In a number of these patients, deep

infection will result with the potential for the loss of implanted metal-work such as fracture fixation or joint replacement prostheses. This will result in poor outcomes for the patient and in extreme cases, loss of the limb itself. The use of drugs that discourage blood clotting in favour of bleeding may therefore have serious unintended consequences for patients suffering such complications. The risk of amputation, loss of soft tissue coverage and loss of the implant is ten times higher for patients who return to theatre with wound problems post-operatively than for those who do not⁶. In addition to the human cost, the cost to the health service of revision surgery for infection is of the order of £30,000 per patient.

There have been a number of guidelines published regarding thromboprophylaxis regimens in Orthopaedic patients, some with conflicting advice. Aspirin has not been recommended for use by many of these documents however analysis of the National Joint Replacement Registry data indicates no difference in outcomes for arthroplasty patients treated with Low Molecular Weight Heparin injections or Aspirin^{7,8}. Many guidelines have advocated the routine use of new chemical thromboprophylaxis agents that do not have a long track record in clinical practice.

There have been several clinical studies from both the UK and North America that have shown that adopting a blanket policy of offering all elective arthroplasty patients chemical thromboprophylaxis has resulted in more complications and poorer outcomes for patients than previous regimens that did not include the routine use of such drugs^{7,9}.

There are a number of new chemical agents available for thromboprophylaxis that report low rates of 'major bleeding' in the published summaries of clinical trials using those drugs. However these trial summaries do not highlight a much larger group of bleeding complications that are termed 'clinically significant non-major bleeds'. These events are reported in small print in the tabulated results sections of those papers^{eg10,11}. It is these events that can seriously jeopardise the results of surgery as detailed above.

A small proportion of patients are at increased risk of developing venous thrombosis when compared to the rest of the general population. Many are identifiable in advance of surgery on account of thrombophilia diagnoses such as previous personal or family history of Venous Thromboembolism, Protein S or Protein C deficiency, Factor V Leiden, Antiphospholipid Antibodies etc. Such patients will almost certainly need some form of chemical thromboprophylaxis in addition to the mechanical methods employed for 'standard risk' patients.

Key to the successful management of risk of Thromboembolism in Trauma and Orthopaedic patients is a personal assessment of each patient on admission and a tailored regimen of mechanical and / or chemical thromboprophylaxis. It is important that the risk of DVT be reduced without increasing the risks of poor surgical outcomes as a result of complications caused by the prophylaxis regimen. To this end, latest advice from the American Academy of Orthopaedic Surgeons recommends mechanical and / or chemical thromboprophylaxis^{12,13}.

The Welsh Orthopaedic Society believes that it is imperative that each patient is assessed pre-operatively for their individual risk of venous thrombosis versus bleeding. These risks together with the options available for prophylaxis should be discussed with the patient. A decision should then be

made on the appropriate thromboprophylaxis regimen. This decision should be based on the balance of benefit versus risk for each individual patient. Once the decision is made it should be recorded in the patient record. We would submit that for 'standard risk' patients that regimen would be based on maintaining hydration, mechanical devices and early mobilisation. Some patients may undoubtedly benefit from additional chemical agents and this should be determined after their individual assessment takes place.

References

- 1: Cusick LA, Beverland DE.
The Incidence of Fatal Pulmonary Embolism after Primary Hip and knee Replacement in a consecutive series of 4253 patients.
J Bone Joint Surg (Br) 2009 91-B 645-8.
- 2: Freedman KB et al
A Meta-Analysis of Thromboembolic Prophylaxis Following Elective Total Hip Arthroplasty*
JBJS(Am) 2000 82-A(7),929-938
- 3: Tasker A, Harbord R, Bannister GC
Meta-analysis of low molecular weight heparin versus placebo in patients undergoing total hip replacement and post-operative morbidity and mortality since their introduction.
Hip Int. 2010 Jan-Mar;20(1):64-74
- 4: Mehta JS, Nicholou N, Kiryluk S and Fordyce MJF.
Venous Leg Ulcers after hip replacement; a clinical evaluation at 5 – 12 years.
J Bone Joint Surg (Br) 2003 85-B 960-2.
- 5: Muller SD, Khaw FM, Morris R, Crozier AE and Gregg PJ.
Ulceration of the lower leg after total knee replacement: a five year review.
J Bone Joint Surg (Br) 1991 83-B 1116-8.
- 6: Galat DD, McGovern SC, Larson DR, Harrington JR, Hanssen AD and Clarke HD.
Surgical Treatment of Early Wound Complications following Primary Total Knee Arthroplasty.
J Bone Joint Surg (Am) 2009 91-A 48-54
- 7: Jameson SS, Bottle A, Malviya A, Muller SD and Reed MR.
The impact of national guidelines for the prophylaxis of venous thromboembolism on the complications of arthroplasty of the lower limb.
J Bone Joint Surg (Br) 2010 92-B 123-6
- 8: Podium presentation BASK annual conference Derby April 2012.
Paper in Press with J Bone Joint Surg (Br)
- 9: Burnett RS, Clohisy JC, Wright RW, McDonald DJ, Shively RA, Givens SA, Barrack RL
Failure of the American College of Chest Physicians-1A protocol for lovenox in clinical outcomes for thromboembolic prophylaxis.
J Arthroplasty 2007 Apr;22(3):317-24
- 10: Eriksson BI et al (for the RECORD 1 study group)
Rivaroxaban versus Enoxaparin for Thromboprophylaxis after hip Arthroplasty.
New England Journal of Medicine 2008 358(26) 2765-76

11: Eriksson BI et al (for the RE MODEL study group)

Oral Dabigatran Etixilate vs subcutaneous enoxaparin for the prevention of venous thromboembolism after total knee replacement: the Re-MODEL randomised trial.

J Thrombosis and Haemostasis 2007 5: 2178-85

12: Jacobs J et al

Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty

J Bone Joint Surg Am. 2012;94:746-7

13: Editorial

Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Total Hip and Knee Arthroplasty

J Bone Joint Surg Am. 2012;94:673-4