CLINICAL GUIDELINE FOR REGIONAL ANAESTHESIA AND THE USE OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) IN THE PERIOPERATIVE PERIOD

1. INTRODUCTION

LMWH have been proven to be effective in reducing the risk of perioperative thrombotic events. Thromboprophylaxis regimens have been influenced by reports of neurological complications associated with the concomitant use of LMWH and neuraxial anesthesia. Obvious problems with understanding this complication are its low incidence and that it can also occur in patients given regional anesthesia but who are not receiving LMWH.

Despite the continued controversy over the benefits of regional anesthesia, there is enough solid data to suggest that use of perioperative neuraxial and peripheral regional anesthesia will improve patient-oriented outcomes.(5,6) The risk of spinal haematoma is a rare but devastating event. The incidence of spinal haematoma is commonly quoted as 1:150,000 epidural anaesthetics and 1:220,000 spinal anaesthetics but may have been as high as between 1:1,000 and 1:10,000 after the introduction of LMWH. By taking into account the pharmacology of LMWH and providing recommendations for the timing of their administration and subsequent neurological monitoring, the guidelines on neuraxial anesthesia and anticoagulation will assist clinicians in minimizing the risks of spinal haematoma development.
(for further information see appendix)

2. PURPOSE

These guidelines should help to allow a careful, balanced and documented discussion of the risks and benefits of regional and general anaesthesia that is individualized to each patient.

3. SCOPE

These guidelines are meant to assist clinicians, anaesthetists, surgeons and pre-assessment nurses in the management of administration of LMWH during the peri-operative period.

4. GUIDELINE

4.1 <u>Spinal, epidural and peripheral nerve block</u>

1. To prevent confusion, the guidelines for epidural, spinal and regional anaesthesia should be the same.

2. Prescribing of all LMWH for these patients should be at 6pm.

Routine Thromboprophylaxis with LMWH for "Moderate" risk patients as defined in the guidelines for LMWH from 13th September 2004

3. If Enoxaparin (Clexane) is to be used, it should be given at a minimum of 10 hours before the conduct of a spinal / epidural / regional injection.
   If a gap of 10 hours is not feasible, (e.g. for day cases or patients being admitted on the day of surgery) then it should be given 2 hours **after** the end of surgery and / or spinal / epidural or peripheral nerve block.

4. Epidural and regional anaesthetic catheters should be removed at a minimum of 10 hours after the previous dose of Enoxaparin (Clexane). 2 hours should elapse before the next dose.

Routine Thromboprophylaxis with LMWH for "Very High" risk patients as defined in the guidelines for LMWH from 13th September 2004

5. These patients are likely to be having Fondaparinux (Arixtra) 6 hours after surgery.

6. Patients who have a dose of Enoxaparin (Clexane) of greater than 1mg / kg body weight or who have Fondapainux, should have their spinal or epidural block delayed until approximately 24 hours after their last dose. A further dose should be delayed 2 hours.

5. SUPPORT

Study Group

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6. EVIDENCE

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7. ENDORSEMENT

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9. Appendix (17):

The knowledge that most perioperative deep vein thromboses begin their development during surgery has motivated the preoperative institution of prophylaxis. This practice has been established and shown effective in Europe for over 40 years. LMWH's are routinely used for prophylaxis, starting either the evening before or several hours before surgery. Bleeding complications have not been a serious problem with this European regimen, and the safety of LMWH's has been documented in a number of reviews and meta-analyses.(1,2)
In recent years, 2 observations have influenced the previously mentioned view. First, American colleagues especially have started prophylaxis postoperatively because of the fear of intraoperative bleeding problems, and this has been shown to be effective and without risk. One randomized study showed no important differences between pre- and postoperative institution of prophylaxis.(3) To have an optimal effect, however, the window to start prophylaxis seems to be between 24 hours before the start of surgery up to 6 hours after its completion.(4) Second, thromboprophylaxis regimens have been influenced by reports of neurologic complications associated with the concomitant use of LMWH and neuraxial anesthesia. Obvious problems with understanding this complication are its low incidence and that it can also occur in patients given regional anesthesia but who are not receiving LMWH. Because a conventional randomized study would require perhaps hundreds of thousands of patients to determine true incidence, the size of this problem is essentially estimated from 4 sources:

1. Analysis of published studies in which LMWH's have been used and the type of anesthesia is reported: there are some 25,000 patients that could be analyzed in this manner, none of whom have identifiable complications.

2. Case reports in the literature: of the approximately 60 such patients reported, most are from the United States, and the majority received Enoxaparin. One important difference between the European and United States experience is the 50% higher dose of Enoxaparin used in the United States (30 mg twice daily v 40 mg once daily in Europe).

3. Calculations from cases reported to LMWH manufacturers give a very low incidence—somewhere around 1 per million. Underreporting, however, can be suspected.

4. Questionnaires to anaesthesiology societies have typically not been specific enough to permit accurate calculation of incidence.

Although the risk of spinal haematoma is far less than that of fatal pulmonary embolism without prophylaxis, it is important to minimize any risk of iatrogenic complications. Today, many countries have guidelines on how to deal with the combination of LMWH and neuraxial anaesthesia. From a surgeon's viewpoint, those found in the Sixth American College of Chest Physicians Consensus Conference on Antithrombotic Therapy or the currently reported ASRA guidelines seem quite reasonable to follow.

Perspectives on the Risks and Benefits of Regional Anesthesia

A principal goal of the ASRA guidelines on neuraxial anaesthesia and anticoagulation is to decrease the risk of spinal haematoma, a rare but devastating event. The incidence of spinal haematoma is commonly quoted as 1:150,000 epidural anaesthetics and 1:220,000 spinal anaesthetics but may have been as high as between 1:1,000 and 1:10,000 after the introduction of LMWH into North America and before the Food and Drug Administration warning and development of the 1998 ASRA consensus statements. When discussing the risks of spinal haematoma, we often neglect to remember the potential benefits of neuraxial and peripheral regional anesthesia. Despite the continued controversy over the benefits of regional anesthesia, there is enough solid data to suggest that use of perioperative neuraxial and peripheral regional anesthesia will improve both "traditional" clinically oriented and "non-traditional" patient-oriented outcomes.(5,6) A meta-analysis of randomized trials revealed that the use of perioperative neuraxial anaesthetic techniques can - decrease mortality (particularly in orthopaedic patients) by approximately 30%, the odds of developing deep venous thrombosis by 44%, pulmonary embolism by 55%, pneumonia by 39%, respiratory depression by 59%, and the need for transfusion by 55%.(7) meta-analyses and more recent randomized trials have also suggested that the use of perioperative neuraxial techniques will significantly decrease the incidence of pulmonary,(80) cardiovascular,(9) and coagulation-related (10) complications in high-risk surgical patients. Use of perioperative epidural analgesia facilitates return of gastrointestinal function and generally results in superior analgesia.(11) Finally, using perioperative regional anesthesia may improve patient satisfaction,(12) health-related quality of life,(13) and possibly reduce the incidence of chronic pain postoperatively.(14)

Thus, there are both risks and benefits to neuraxial anesthesia, the extent of which may be difficult to quantify as we attempt to individualize the risk/benefit ratio for each of our patients. By taking into account the pharmacology of anticoagulants and providing recommendations for the timing of their administration and subsequent neurological monitoring, the updated ARSA statements on neuraxial anesthesia and anticoagulation will assist clinicians in minimizing the risks of spinal haematoma development. In our current litigious environment, the intuitive reaction of some clinicians would be to avoid neuraxial anesthesia in any patient taking anticoagulants; however, this would ignore the many significant benefits of regional anesthesia (especially in high-risk patients). Furthermore, the avoidance of regional anesthesia often necessitates the administration of general anesthesia, which is not without its own risks.(15) A careful, balanced and documented discussion of the risks and benefits of regional and general anesthesia that is individualized to each patient would be the most prudent course of action. The ASRA guidelines are therefore valuable in guiding our contemporary anaesthetic practice.