Trust Guideline for the Management of: Regional Anaesthesia (Spinal and Epidurals) in patients receiving Venous Thromboembolism Prophylaxis, Anticoagulant and Antiplatelet Drugs

Document Control:

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V2.0	October 2016	Service Director Critical Care (NNUH)	No clinical changes
V3.0	July 2020	Service Director Critical Care (NNUH)	Guidance on Direct Oral Anticoagulants (DOACs) added and references updated. Edoxaban added to the list of anticoagulants on the Epidural / Paravertebral / Interscalene brachial plexus Catheter Risk Assessment Tool in the Appendix.

V4.0	March 2024	Clinical Effectiveness and Quality Assurance Facilitator	Update into new template Document no longer joint with JPUH

Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
None	Not applicable

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:

- Chief of Anaesthesia and Theatres (NNUHFT)
- Consultant/ Chief of Surgery (NNUHFT)

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a clinical guideline applicable to Norfolk and Norwich University Hospitals NHS Foundation Trust; please refer to local Trust's procedural documents for further guidance, as noted in Section 5.

Contents Page

Quick reference (optional)

a. **Low Molecular Weight Heparin (LMWH): Dalteparin ≤5000U, Tinzaparin ≤ 4500U or Enoxaparin ≤ 40mg S/C daily.**

If LMWH administered before block:	Wait at least 12 hours before block insertion.
If block insertion before LMWH:	Wait at least 4 hours before LMWH administration.
Epidural catheter removal:	Wait at least 12 hours since last dose and 4 hours before next dose of LMWH.

Administer LMWH at 18:00 so that at least 12 hours normally elapses before surgery the following day.
Removal of epidural catheters should occur between 10:00 and 14:00 to allow suitable intervals between doses of LMWH administered at 18:00. Epidural removal risk assessment tool (Appendix 2) should be used.

b. **Unfractionated heparin (UFH) 5000 IU 8 or 12 hourly**

If UFH administered before block:	Wait 4 hours before block insertion.
If block inserted before UFH:	Wait 1 hour before UFH administration.
Epidural catheter removal:	Wait 4 hours since last dose and 1 hour before next dose of UFH.

Delay Venous thromboembolism (VTE) prophylaxis if:

a. A hemorrhagic aspirate (i.e. a “bloody tap”) is encountered during the initial neuroaxial needle or epidural catheter placement, delay VTE prophylaxis by 24 hours.

b. When a neuroaxial technique is attempted but abandoned for general anesthesia, patients probably sustain excessive trauma to the epidural space. In this situation, it is better to wait at least 24 hours before initiating LMWH therapy.

c. Patients undergoing surgery in the late afternoon, where there is <4 hours between neuroaxial block insertion and routine LMWH administration time of 18:00, should have their VTE prophylaxis deferred until at least 4 hours have elapsed post epidural/spinal insertion.

Therapeutic doses of both UFH and LMWH, markedly increase the risk of bleeding. Under these circumstances, neuroaxial anaesthesia should not be attempted. Occasionally patients may be therapeutically anticoagulated with UFH or LMWH <u>after</u> neuroaxial catheter insertion. Under no circumstances must these epidural catheters be removed while the patient is therapeutically anticoagulated.

Patients ≤50kg see advice sheet (Trustdocs ID: 1697) **for dose of Thromboprophylactic LMWH. Patients ≤ 50kg who receive a conventional dose LMWH should have their epidural removed after 24 hours.**

Warfarin therapy:
For elective surgery warfarin should be stopped pre-operatively. (Trustdocs ID: 1215)

INR must be ≤ 1.5:

1. Within 24 hours of insertion of spinal/epidural needles and catheters.
2. Whenever the indwelling epidural catheter is in place.

Warfarin should **NOT** be given whilst an epidural catheter is in situ.

c. **Drugs with Antiplatelet activity**: (Trustdocs ID: 9836)

Check indication for antiplatelet agent before stopping. **If coronary artery stents present discuss with cardiologist.**

a. Aspirin, NSAIDs and dipyridamole:

   If used alone, appear to represent no added significant risk for the development of spinal hematoma in patients having epidural or spinal anesthesia.

2. Thienopyridine derivatives e.g. clopidogrel/prasugrel: Stop 7 days before surgery. Do not give whilst epidural in situ.

3. GP IIb/IIIa inhibitors (e.g. abciximab/Tirofiban): Contraindicated with neuroaxial analgesia techniques.

1. Introduction

1.1. Rationale

The incidence of VTE is increased markedly in association with surgery, trauma and immobilised medical patients. Therefore effective VTE prophylaxis is now a standard of care required in these patients[7].

Neuroaxial anaesthesia (spinal or epidural) confer many advantages, including a significant reduction in the incidence of VTE and is commonly practised locally. Anticoagulants may increase the risk of bleeding from vertebral vessels damaged during the insertion of neuroaxial anaesthesia. This can lead to permanent neurological injury if a vertebral canal haematoma develops. Although such an event is devastating, it is an extremely rare occurrence and far more patients suffer from the effects of VTE.

Patients should have the combined benefits of VTE prophylaxis and neuroaxial anaesthesia, with minimal risk of vertebral canal haematoma formation. To this effect, awareness of anticoagulant status and careful coordination of the administration of VTE prophylaxis and neuroaxial anaesthesia insertion is essential. The decision to institute neuroaxial anaesthesia must be made after assessing the risks versus benefits for each individual patient.

Prescribers need to be mindful of the fact that anticoagulants differ greatly in their ability to alter clotting, with different pharmacodynamic and pharmacokinetic properties. Co-morbidities (e.g. renal failure), and concurrent administration of drugs with anticoagulant/antiplatelet activity, may enhance the effects of VTE prophylaxis medication. Careful monitoring for spinal cord compression and prompt effective action in the event of neurological symptoms will enhance safety.

1.2. Objective

The objective of the clinical Guideline is to prevent the occurrence of vertebral canal haematomas when neuroaxial anaesthesia is administered to patients receiving drugs with anticoagulant and antiplatelet activity.

1.3. Scope

This guideline applies to all adult patients (> 16 years old) undergoing spinal or epidural anaesthesia

1.4. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
LMWH	Low Molecular Weight Heparin
UFH	Unfractionated heparin
VTE	Venous thromboembolism
NSAIDs	Non-steroidal anti-inflammatory drugs
DOACs	Direct Oral Anticoagulants
NOAC’s	Non-Vitamin K oral anticoagulants
TSOAC’s	Target-Specific Oral Anticoagulants
AF	atrial fibrillation

NICE	National Institute for Health and Care Excellence
NNUHFT	Norfolk and Norwich University Hospitals NHS Foundation Trust

2. Responsibilities

All anaesthetic, surgical and nursing staff should be aware of the contents of this guideline and ensure appropriate intervals exist between regional anaesthesia (including removal of epidural catheters) and venous thromboembolism prophylaxis, anticoagulant and antiplatelet drugs.

3. Processes to be followed

This guideline should be used in conjunction with Trust guideline CA2029/B17 for the management of adult patients receiving Epidural analgesia (TrustDocs ID: 1911) and guideline CA2060 for the management of adult patients on therapeutic anticoagulation who require elective surgery or an invasive procedure (TrustDocs ID: 1215).

3.1. Low Molecular Weight Heparin (Dalteparin ≤ 5000U, Tinzaparin ≤ 4500U or Enoxaparin ≤ 40mg S/C daily).

If LMWH administered before block:	Wait at least 12 hours before block insertion.
If block insertion before LMWH:	Wait at least 4 hours before LMWH administration.
Epidural catheter removal:	Wait at least 12 hours since last dose and 4 hours before next dose of LMWH.

For the majority of elective patients these criteria will be met by the use of the following dosing schedule.

Administer LMWH at 18:00 so that at least 12 hours normally elapses before surgery the following day.
Removal of epidural catheters should occur between 10:00 and 14:00 to allow suitable intervals between doses of LMWH administered at 18:00. Epidural removal risk assessment tool (Appendix 2) should be used.

3.2. Unfractionated Heparin (5000 U S/C 8 or 12 hourly).

If UFH administered before block:	Wait 4 hours before block insertion.
If block inserted before UFH:	Wait 1 hour before UFH administration.
Epidural catheter removal:	Wait 4 hours since last dose and 1 hour before next dose of UFH.

New to these guidelines is the recommendation that VTE prophylaxis should be delayed by 24 hours if:

1. A hemorrhagic aspirate (i.e. a "bloody tap") is encountered during the initial neuroaxial needle or epidural catheter placement.

2. When a neuroaxial technique is attempted but abandoned for general anesthesia, patients probably sustain excessive trauma to the epidural space. In this situation, it is better to wait at least 24 hours before initiating LMWH therapy.

3. Patients undergoing surgery in the late afternoon, where there is <4 hours between neuroaxial block insertion and routine LMWH administration time of 18:00, should have their VTE prophylaxis deferred until at least 4 hours have elapsed post epidural/spinal insertion.

Therapeutic doses of both UFH and LMWH, markedly increase the risk of bleeding. Under these circumstances, neuroaxial anaesthesia should not be attempted. Occasionally patients may be therapeutically anticoagulated with UFH or LMWH after neuroaxial catheter insertion. Under no circumstances must these epidural catheters be removed while the patient is therapeutically anticoagulated.

3.3. Regional Anaesthesia and Warfarin therapy:

Patients receiving warfarin therapy should have this discontinued ≥ 5 days before the planned surgical procedure (see Trustdocs ID: 1215 for the management of adult patients on therapeutic anticoagulation who require elective surgery or an invasive procedure).

An INR should be checked within 24 hours of the procedure and a value of ≤ 1.5 is considered safe for spinal/epidural insertion. Wafarin therapy is **contraindicated** whilst an epidural catheter is in situ.

3.4. Regional Anaesthesia and drugs with Antiplatelet activity:

Aspirin, NSAIDs and dipyridamole: If used alone these agents appear to represent no added significant risk for the development of spinal hematoma in patients having epidural or spinal anesthesia. At present, there are no specific concerns as to the timing of single-shot or catheter techniques in relationship to the dosing of NSAIDs, postoperative monitoring, or the timing of neuraxial catheter removal.

Thienopyridine derivatives (e.g. clopidogrel/prasugrel): Consensus management is based on labeling precautions and surgical, interventional cardiology/radiology experience. Clopidogrel should be discontinued 7 days before neuroaxial blockade is attempted.

Antiplatelet agents must not be stopped in patients who have coronary artery stents insitu without discussion with a cardiologist.

These agents should not be recommenced in a patient whilst an indwelling epidural catheter is insitu.

GP IIb/IIIa inhibitors (e.g. abciximab), exert potent antiplatelet effects. Accordingly neuroaxial techniques should be avoided until platelet function has recovered. GP IIb/IIIa antagonists are contraindicated within four weeks of surgery. Should one need to be administered in the postoperative period (following a neuroaxial technique), the indwelling epidural catheter should be removed first.

In summary, the concurrent use of other medications which may affect clotting mechanisms may increase the risk of bleeding and hence spinal haematomas if a neuroaxial block is sited. Extra vigilance is required and the patient monitored closely for signs of cord compression (Appendix 1).

3.5. Direct Oral Anticoagulants (DOACs). Also known as Non-Vitamin K oral anticoagulants (NOAC's) or Target-Specific Oral Anticoagulants (TSOAC's) (Trustdocs ID: 8752)

Non-vitamin K oral anticoagulants (dabigatran (Pradaxa®), rivaroxaban (Xarelto®), apixaban (Eliquis®) and edoxaban (Lixiana®)) are options for the prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation (AF). Generally can be stopped 2 days before operation (longer if deranged renal function). Should not be given while epidural catheter insitu.

3.6. Removal of epidural catheters

To ensure safe removal of epidural catheter the trust epidural risk assessment tool should be completed before removal. This is available on all surgical wards where epidural catheters are in routine use. See appendix 2.

3.7. Diagnosis and management of vertebral haematoma

If a haematoma is suspected the guidance in Appendix 1 should be followed.

4. Related Documents

Trustdocs ID: 8752
Trustdocs ID: 1215
Trustdocs ID: 9836
Trustdocs ID: 1697

5. References

1. Wildsmith JAW, McClure JH. Anticoagulation drugs and central nerve blockade. Anaesthesia 1991;46:613-4
2. American society of Regional Anaesthesia. Consensus Statement 2002. www.asra.com
3. American College of Chest Physicians 7th Guidelines on Thromboprohylaxis. Chest 2004
4. Tryba M. European Practice Guidelines: Thromboembolism prophylaxis and regional anaesthesia. Regional Anaesthesia and Pain Medicine 1998;23:178-182
5. Wu CL. Regional Anaesthesia and anticoagulation. J Clinical Anaesthesiology 2001;13:49-58
6. Scottish Intercollegiate Guideline Network. Prophylaxis of Venous thromboembolism 2002. www.sign.ac.uk

7. Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism. NICE guideline [NG89] Published date: 21 March 2018 Last updated: 13 August 2019.

6. Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Adherence to recommended time intervals between Needle insertion and VTE prophylaxis administration	Clinical Audit – audit 20 consequtive cases Ongoing review of relevant Datix reports	Anaesthetic governance team	Anaesthetic directorate	annual
Adherence to recommended time intervals between Epidural catheter removal and VTE prophylaxis administration	Clinical Audit - audit 20 consequtive cases Ongoing review of relevant Datix reports	Anaesthetic governance team	Anaesthetic directorate	annual
Completion of epidural removal risk assessment tool.	Clinical Audit - audit 20 consequtive cases Ongoing review of relevant Datix reports	Anaesthetic governance team	Anaesthetic directorate	annual

The audit results are to be discussed at relevant governance meetings to review the results and recommendations for further action. Then sent to Anaesthetic Directorate who will ensure that the actions and recommendations are suitable and sufficient.

7. Appendices

Appendix 1: Vertebral/Spinal Haematomas complicating Neuroaxial anaesthesia

Although spinal haematomas in this setting is rare, it nevertheless could have a potentially devastating neurological outcome if not recognized early.
The following factors have been implicated in increasing the risk of spinal haematoma formation:

1. Frail, elderly females.
2. Associated haemostatic disorder.
3. Technically difficult insertion requiring multiple attempts at multiple levels.
4. Bloody tap i.e. blood in needle or epidural catheter.
5. Inappropriate doses or timing of LMWH.
6. Combination of drugs with anticoagulant/antiplatelet effects.
7. Removal of epidural catheter: 30-60% of clinically important haematomas occur after catheter removal. Most occur within 24 hours of catheter removal, but may occur up to 6 days later.

If neuroaxial anaesthesia was difficult or associated with haemorrhage, this should be documented and the patient monitored particularly closely for evidence of cord compression. Moreover, it is the recommendation of these guidelines that VTE prophylaxis should then be delayed for 24 hours.

Detection:

The symptoms and signs of spinal cord compression closely resemble the effects of a dense spinal or epidural block, which compounds the diagnostic accuracy. Therefore to assess the neurological function in the postoperative period, it is advisable to use infusion of opioids or low concentrations of local anaesthetic.

Medical staff, nursing staff and the patient must be made aware of what symptoms and signs to lookout for (patient information leaflet) so that the alarm can be raised. New onset of one or more of the following is suggestive of spinal cord compression.

1. Increasing motor weakness despite a constant epidural infusion rate.
2. Increasing sensory weakness despite a constant epidural infusion rate.
3. Cauda Equina signs i.e. Bladder and bowel incontinence.
4. Back pain which is often of sudden onset and “excruciating”.
5. Radicular pain due to irritation of nerve roots by blood.

Golden rules to be aware of:

- The patient MUST be able to move something on his legs, even if just dorsiflexing his toes or foot, the WHOLE time an epidural is running in the postoperative period.
- Movement should return 2-3 hours after a local anaesthetic bolus.

- Thoracic epidurals should be associated with little or no lower limb motor weakness.

Treatment:

This is a medical emergency, as spinal cord compression is likely to lead to permanent neurological injury if not surgically decompressed within 8 hours. The sooner the problem is recognised the sooner the surgery can be undertaken. If spinal heamatoma is suspected stop epidural infusion and contact the on-call anaesthetist who will then liaise with the Consultant Spinal Surgeon and Radiologist to arrange an MRI followed by surgery if indicated.'

Pain Assessment and Observation frequency guidance	Addressograph

:	
Epidural PCA: Oral/IM/SC analgesia	Hourly for 8 hours 2 hourly for 48 hours 4 hourly thereafter

	Once per shift 1 hour after analgesia	

Pain	Sedation	Nausea	Catheter site	Leg Movement	
0	No pain	Alert	None	Clean	Full movement
1	Mild pain on mov	Mild: Easy to rous	Mild nausea	Skin reddening, N	Weakness of plantar flexion

	ement	e		oinduration	
2	Moderate pain on movement	Easy to rouse, often drowsy	Nausea and retching	Skin induration No discharge	Weakness of hip flexion
3	Severe pain on movement	Somnolent. Difficult to rouse	Vomiting	Discharge from cathether	Unable to move legs

	Date/time or 24 clock	00	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23
Pain	3																								
	2																								
	1																								

	0																								
Sedation	3																								
	2																								
	1																								
	0																								
Nausea	3																								
	2																								
	1																								
	0																								
PCA	Tries																								
	Good																								
	Resp																								
	Total																								
Epidural	Rate																								
	Site																								
	LegMvmt																								
	Resp																								
	Total																								
	Signature																								

Appendix 2: Pain Assessment and Observation Frequency Guideline

Appendix 3: Epidural / Paravertebral / Interscalene brachial plexus Catheter Risk Assessment Tool

Patient Name: **Hospital Number:**

Before removing an epidural / paravertebral / interscalene brachial plexus catheter please answer all the questions below:

Question	Yes	No
A. Heparin		
1. Is the patient prescribed Dalteparin (Fragmin) greater than 5,000 units or Tinzaparin (Innohep) dose greater than 4,500 units or Enoxaparin (Clexane) greater than 40 mg		
2. Has any heparin (Dalteparin, Tinzaparin, Enoxaparin or Unfractionated Heparin -sc or iv) been given in the last 12 hours?		
3. If the patient weighs less than 50 kgs have they received **any** heparin in the last **24** hours?		
B. Other anti-coagulant or anti-platelet Drugs		
4. Has Warfarin been given within the past 2 days?		
5. For patients who received Warfarin in the last week – is the INR greater than 1.5 **on the day of removal**?		
6. Has the patient received Rivaroxaban within the last 18 hours?		
7. Has the patient received Fondaparinux or Dabigatran within the last 36 hours?		
8. Has Clopidogrel or Prasugrel been given within the past 7 days?		
9. Is the patient taking Aspirin doses greater than 300mg per day?		
10. Is the patient taking any other anticoagulants or anti-platelet drugs**?		
C. Early Warning Score		
11. At time of assessment does the patient trigger the Early Warning Score (EWS)?		

If the answer is YES to any of the questions, DO NOT remove the epidural, PVB or brachial plexus catheter Seek advice from the Pain Team on Bleep 0571 or the On-call Anaesthetist

If unable to remove (any YES response) please document the name of the person contacted and advice given:

Signature: **Date** **Time:**

Epidural / paravertebral / interscalene brachial plexus catheter removed?

Print Name: **Signature:**

Date: **Time:**

Patient Information Leaflet given? **Yes ☐** **Signature:**

Dose Post Removal Advice: Drugs may be restarted after the following time intervals

4 hours: Unfractionated Heparin, Warfarin
4-6 hours: Dalteparin, Tinzaparin, Enoxaparin

Next day: Rivaroxaban, Dabigatran, Fondaparinux, Clopidogrel, Aspirin, Prasugrel

** Other anti-coagulant and anti-platelet agents include (this is not an exhaustive list):
Abciximab, Acenocoumarol, Apixaban, Bivalirudin, Danaparoid, Edoxaban, Epoprostenol, Idraparinux, Phenindione, Ticagrelor, Tirofiban

For further information see Adult Patients Receiving Epidural Analgesia Trustdocs ID: 1191

8. Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Surgical	**Department**	Anaesthesia
Name of person completing form	Akesh Dhrampal	**Date**	26.7.24

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	None			NO
Pregnancy & Maternity	None			NO
Disability	None			NO
Religion and beliefs	None			NO
Sex	None			NO
Gender reassignment	None			NO
Sexual Orientation	None			NO
Age	None			NO
Marriage & Civil Partnership	None			NO
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?	NA			

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.