Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CUH
Ospidéal Ollscoile Chorcaí
Cork University Hospital

Policy and Procedure for the management of patients presenting with excessive anticoagulation (INR>5.0) while on Vitamin K antagonists e.g. warfarin at the Cork University Hospital Group.

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1 Policy Statement

Patients on warfarin presenting with an INR above 5.0 should be managed in accordance with the procedure outlined below.

2 Purpose

To ensure the safe management of the patient presenting with excessive anticoagulation while on warfarin

3 Scope

All medical staff working in the Cork University Hospital Group.

4 Legislation/Related Policies

Protocol on dose adjustment of oral anticoagulant therapy by a registered nurse in the out patients department. (PPG-CUH-CUH-50)

Policy and procedure on the management of patients on oral anticoagulant therapy at the Cork University Hospital Group. (PPG-CUH-NUR-9)

Policy and Procedure for the Prescribing, Ordering and Administration of Prothrombin Complex Concentrates (PCC) in Cork University Hospital. (PPG-CUH-CUH-42)

5 Glossary of Terms and Definitions

5.1 International Normalised Ratio (INR)

Is a system established by the World Health Organization and the International Committee on Thrombosis and Haemostasis for monitoring and reporting blood coagulation. Under this system, results are standardized using the International Sensitivity Index for the particular test reagent/instrument combination used.

5.2 Oral Anticoagulant Therapy

Vitamin K antagonists which includes warfarin (BCSH, 2005)

5.3 Warfarin

A vitamin K antagonist that results in reduced biological activity of the vitamin K dependent clotting factors II, VII, IX and X, as well as proteins C and S, hence prolonging the clotting time (Fitzmaurice DA & Murray ET, 2005). Warfarin is the most commonly used Vitamin K antagonist in Ireland.

5.4 Titration

The incremental increase/decrease in drug dosage to a level that provides the optimal therapeutic effect (Mosby, 2004)

5.5 PCC

Prothrombin Complex Concentrate (PCC) **is not routinely** administered to reverse excessive anticoagulation in the absence of bleeding but should be administered in life threatening major haemorrhage or if immediate urgent reversal is required to allow for surgery or an interventional procedure. PCC is more effective than Fresh Frozen Plasma (FFP) for reversal of bleeding associated with excessive anticoagulation, therefore FFP is not indicated or recommended when PCC is available.

5.6 BCSH

British Committee for Standards in Haematology.

6 Roles and Responsibilities

6.1 The doctor ordering the INR sample is responsible for checking the INR result and acting in accordance with the policy and procedure outlined above.

6.2 Responsibility for complying with the policy

The doctor ordering INR sample and prescribing appropriate treatment for excessive anticoagulation is responsible for:

- Having the necessary evidence-based knowledge and skills to ensure the delivery of safe care.
- Ensuring that he/ she is aware of and adheres to the contents of this policy.

6.3 Responsibility for ensuring compliance with the policy

The Consultants are responsible for:

- Implementing this policy
- Communicating policy to all new members of their team

7 Procedure

It is important to assess all patients presenting with an INR result out of range to determine if he/she has taken his/her medication as instructed, if he/she has commenced any new medication which may interact with warfarin and if he/she has any risk factors for bleeding.

7.1 INR 5.0 – 8.0 No bleeding

- Stop warfarin for 1-2 days.
- Recheck INR after 1-2 days.
- If there are risk factors for bleeding, recheck INR level within 24hrs.

- Restart warfarin at reduced dose when INR < 5.0
- Determine if there are any causative or contributing factors for the increase in the INR level and adjust dose accordingly (see appendix A, Dosage Adjustment Chart)

7.2 INR 5.0 – 8.0 minor bleeding

- Stop warfarin for 1-2 days.
- Consider administration of low dose Vitamin K 1-2mgs sublingually depending on extent of bleeding and risk factors for further bleeding. A low dose of vitamin K (see appendix 1), e.g.1-2mgs of the paediatric intravenous preparation, can be administered sublingually. For patients with prosthetic heart valves caution should be taken to avoid over correction of the INR below therapeutic range.
- Restart warfarin at reduced dose when INR < 5.0
- Determine if there are any causative or contributing factors for the increase in the INR level and adjust dose accordingly
- If INR is over-corrected contact Haematology team for dosing instructions and advice.

7.3 INR greater than 8.0

- Stop Warfarin
- Identify additional risk factors for bleeding: increasing age (e.g. > 70 yrs), previous bleeding event/complications (ulcers, wounds, post surgery)
- Check for evidence of minor bleeding: epistaxis, bleeding gums, haematuria, oozing wounds, haemoptysis, PR bleeding.
- Administer 1-2mgs of Vitamin K sublingually. A low dose of vitamin K, e.g.1-2mgs of the paediatric intravenous preparation, can be administered sublingually. **For patients with prosthetic heart valves caution should be taken to avoid over correction of the INR below therapeutic range.**
- Recheck INR within 24hrs and restart warfarin **at a reduced dose once INR < 5.0.**
- **If there are no risk factors identified or there is no evidence of minor bleeding recheck INR** within 24hrs.
- Determine if there are any causative or contributing factors for the increase in the INR level and adjust dose accordingly.
- If INR remains > 8.0 after 24hours the dose of Vitamin K can be repeated.
- If INR is over-corrected contact Haematology team for dosing instructions and advise.

7.4 Emergency reversal of warfarin in the event of major/life threatening haemorrhage.

- Stop warfarin
- Consult with Haematology consultant/registrar and Cardio-thoracic consultant/registrar if there is a mechanical valve *in-situ*.
- Administer Prothrombin Complex Concentrate (PCC) *Octaplex* as per the manufactures instructions; refer to **"Policy and Procedure for the Prescribing, Ordering and Administration of Prothrombin Complex Concentrates (PCC) in Cork University Hospital" (PPG-CUH-CUH-42).**
- Administer 5mgs of Vitamin K intravenously (IV Vitamin K will provide 70% correction of INR within 8 hours). **For patients with prosthetic heart valves caution should be taken to avoid over correction of anti-coagulation below therapeutic range. A low dose of IV Vitamin K (1-2mgs) can be administered sublingually. Discuss with cardio-thoracic, cardiac or haematology consultant or registrar <u>before</u> administering Vitamin K.**
- Note: there may be an increased risk of bleeding when obtaining intravenous access due to high INR.
- Recheck INR within 30-mins to 1 hour of administration of PCC. There may be an initial correction of the INR shortly after administration of PCC however this may be temporary due to the half-life of factor VII in PCC.
- The INR should be repeated 6hrs post administration of PCC and regularly until the patient's INR is within their target range.
- Further Vitamin K may be required.
- Warfarin should be re-commenced once patient is haemodynamically stable
- If INR is over-corrected, contact Haematology team for dosing instructions and advise.

8 Implementation Plan

- The policy and supporting evidence will be made available to all wards/units through Q-PULSE system.
- Orientation to all new staff will be undertaken regarding this by Consultant Haematologist

9 Revision and Audit

Revision

This procedure will be reviewed on a 2 yearly basis or earlier if indicated.

Audit

An audit will be carried out when this document is due revision

10 References/Bibliography

Bristish Committee for Standards in Haematology: Guidelines on Oral Anticogulation with warfarin – fourth edition (2011).

British National Formulary (Sept 2011).

11 Appendices

11.1 Appendix 1 Information on Vitamin K

Either of two naturally occurring fat-soluble vitamins $C_{31}H_{46}O_2$ and $C_{41}H_{56}O_2$ essential for the clotting of blood because of their role in the production of prothrombin —called also *vitamin K_1, vitamin K_2* (Medline plus medical encyclopaedia). Vitamin K is the first drug of choice to be administered for the reversal of excessive anti-coagulation **if the patient has evidence of bleeding.**

Vitamin K is dispensed in ampoules of 1ml/10mgs known as Konakion®, or 0.2mls/2mgs known as paediatric Konakion®. This can be administered sublingually using a 1ml syringe and a filter needle to draw up and administer the solution.

Vitamin K is also available in 10mg tablets for oral administration.

When **partial correction** is required to achieve a ta**r**get therapeutic INR, the Intravenous preparation of Vitamin K can be administered in low doses of 1-2mgs sublingually.

5mgs of Vitamin K will **completely reverse** anticoagulation, which is only indicated if the patient is presenting with bleeding as a result of a high INR. **Particular caution** is advised for patients with **prosthetic heart valves**, where the use of vitamin K may increase the risk of thrombosis due to overcorrection of the INR. Therefore, if indicated, **small doses of vitamin K only (e.g. 1 – 2 mg**) are recommended.