Audit of oral anticoagulant therapy post-Cardiac Surgery at the Golden Jubilee National Hospital

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Introduction

According to The National Patient Safety Agency (NPSA) there have been 480 reported cases of harm or near harm from the use of anticoagulants including 120 deaths in the UK (1990–2002). Deaths from the use of Warfarin were responsible for 77% (92) of cases.¹

Patient safety alert 18 from the NPSA entitled “actions that can make anticoagulant therapy safer” was released on the 28th March 2007.² The recommendations under procedures and clinical protocols indicate that, health organisations should have written procedures and clinical protocols for the safe use of oral anticoagulant therapy. These procedures should include guidance on a system for documenting results and treatment, safe initiation of anticoagulant therapy including the use of low dose loading and how to monitor and adjust maintenance therapy to safely achieve target INR. These national recommendations may be applied to different indications and geographic locations. They also include a list of safety indicators and clinical outcome measures with recommendations for particular observations.

We have adapted the recommendations of the NPSA audit checklist to assess safety and efficacy of our service with respect to oral anticoagulant therapy in our cardiac patients. In the winter of 2008 a number of cardiothoracic centres in The Greater Glasgow and Clyde joined to form a united regional centre at The Golden Jubilee National Hospital NHS trust (GJNH). A number of different protocols were therefore available to us from each centre. This provided us with an opportunity to standardise our management of oral anticoagulation in order to improve patient safety and quality of care.

We propose to design an oral anticoagulation prescription chart specifically for prescribing, monitoring and recording of Warfarin therapy in our cardiac unit. This chart will contain information in the form of a protocol that should make the management of patients on Warfarin safer and more reliable.

Audit aims

To audit INR documentation and Warfarin prescription
To audit the loading therapy (First two doses)
To audit the maintenance therapy (Until discharge)
To compare findings with standards set by the British Committee for Standards in Haematology
To suggest improvement to the current prescription by preparing a safe protocol
Objectives

To collect data using a proforma
To collect retrospective data from patients records after discharge from hospital
To develop a system that allows the information obtained from completed charts to be scored based on its level of importance for patients initiated on Warfarin
To analyse the data and look for prescription patterns by procedure and by consultant
To present the findings in a clear and logical manner
To make any meaningful findings available to others within the region and beyond

Standards

The British Committee for Standards in Haematology outlined standards for auditing oral anticoagulation use. Extensive audit indicates that only 50% of INRs in a population of patients taking Warfarin are usually within range (i.e. 0.5 units of target INR) at any one time. Whereas only 80% of patients are within 0.75 of the target. 3 This leaves less than 20% > than 1 unit as acceptable. According to the NPSA these values as well as clinical outcomes such as mortality and morbidity from Warfarin therapy may be used as standards for anticoagulant audit.

Method

A proforma was constructed in order to collect information on patient’s initiation and maintenance on Warfarin post operatively. All post operative cardiac patients commenced on Warfarin were included in this audit for the months of September and October 2008. Data was retrospectively collected from patient records and tabulated in Excel before being transformed to SPSS data editor (Version 15.0). The first two doses were considered as the loading dose and the rest as maintenance. Data on patient age, sex, ventricular and liver functions, drug interactions and the INR on starting the Warfarin were also collected. The target was achieved when the INR was in range (Within 0.5 units). A note of any complications related to Warfarin therapy was made.

Results

Initiation of anticoagulant therapy A total of 38 patients were initiated on Warfarin during this two-month period. Four case notes / Warfarin prescription charts were missing. In 15% (6) of prescriptions the indication for anticoagulation was vague hence non compliant with standards for clear documentation and prescription. With the exception of one group of patients who received 3 mgs loading irrespectively, no other patient followed a loading dose protocol. None of the patients followed a maintenance protocol. The Median loading dose was however 5 mgs ranging from 1.5-7.5 mgs.

Maintenance therapy In total 279 INR values were documented. The number of patients reaching therapeutic levels peaked on day 5 (Demonstrated by histogram). On the fifth day only 39% of INRs were within 0.5 INR units and 64% were within 0.75 INR units. In 24% the INR was greater than 1 units from the target. We were closest to being compliant with the standards on day 7 with 50,71 and 14% INR units respectively.
Complications  There were three incidences of Warfarin related GI bleeding (8%). One required intervention by Endoscopy and two settled after reversal of Warfarin and conservative treatment. There were no thrombotic complications. Indicating that the patients were at higher risk by being over anti-coagulated than under anti-coagulated.

Discussion

This audit shows that compared with the standards set above, the target therapeutic anticoagulation therapy at GJNH is not fully compliant with the national guidelines. GJNH has no standardised guidelines or protocols in place for safe initiation and maintenance of Warfarin therapy. Great lee’ way has been given to doctors to use their clinical judgment to adjust levels. Until protocols have been written and put into effect, it can be expected that the Hospital will continue to not be fully compliant when audited with the same standards as above.

The guidelines by the British Committee for Standards in Haematology recommends a loading dose of 10 and 10 mgs to be adjusted in the presence of advanced age, poor cardiac or liver function or when co-administered with medications mentioned above. Most drug interactions result in an increased anticoagulant effect. The vast majority of our patients are of advanced age. Cardiac and liver dysfunctions are commonly encountered in our patients and cardiac surgical patients are frequently on multiple medicine that lower the tolerance to Warfarin. These include Aspirin, Amiodarone, Omeprazole, Simvastatin and antibiotics for wound or other hospital-acquired infections. Therefore unless the patient is a young man on Rifampicin, Phenobarbitone, Carbamazepine or Phenytoin, all post operative cardiac patients requiring Warfarin should be loaded cautiously and with a reduced dose in comparison to the loading schedule suggested by the British Committee for Standards in Haematology.

In general the desired days to reach therapeutic INR levels is day four or five. By this day the pacing wires are usually removed and the plan for discharge can begin. The diagrams 1-a&b illustrate the distribution of patients and the time to reach target therapeutic levels in days. The patients in diagram a on the left received 5-6 mgs as a loading dose. The mean days to reach target range were 5.2 days. This illustrates a normal distribution. One patient in this loading group suffered a GI bleed as a direct result of increased INR. The diagram b on the right illustrates the time to reach therapeutic target range with a loading dose of 3-4 mgs as observed in this audit. The mean days to reach target range was 5.6 days. There was no significant statistical difference in the days to discharge between the two groups ($p = 0.7$). It would therefore not be totally illogical to use the latter dose in patients who have multiple additional predispositions to Warfarin sensitivity. However the number of patients in the 3-4 mg group was too small to make a meaningful statistical comparison. The scatter plot below (Diagram 2) illustrates almost no linear statistical correlation between the Warfarin loading dose and days to reach target INR (Pearson correlation, $r = 0.03$).

It is quite clear that Warfarin anticoagulation is characterised by marked variability. It is largely affected by environmental and host factors and may be more effective and safer if it incorporates genetic polymorphisms such as CYP2C9 or VKORC1
genotyping. There is level Ib evidence in support of CYP2C9 genotyping as a guide to Warfarin prescribing to enhance the efficiency and safety of anticoagulation. Although genetic based computer assisted dosing is practiced in a number of centres worldwide, a simple genetic algorithm acceptable to clinicians and validated in a diverse population including post cardiac surgical patients is the next desired step.

Diagram 1 a (Left) & b (Right): The distribution of patients and the time to reach target therapeutic levels in days for low (5-6 mg) and ultra low (3-4 mg) doses of Warfarin.

Diagram 2: The scatter plot illustrating almost no linear relationship between the Warfarin loading dose and days to reach target INR.
Recommendations

Prescription chart:
Additional information on the prescription chart to instruct users if the reduced dose regime is to be used or if a non-guideline dose for Warfarin is requested by the consultant in charge of the patient.

Warfarin induction and maintenance:
To implement a clear protocol for induction and maintenance therapy, which may be updated if required.
To suggest guidelines for the management of complications.

Genotype-guided Warfarin prescribing:
To investigate by means of a pilot experiment and assess feasibility of using this test in order to incorporate genetic polymorphism as a host factor to determine predisposition to Warfarin sensitivity prospectively.

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References


