An Investigation of the Management of the International Normalised Ratio (INR) in Warfarin Therapy During the Initial Five Months of Treatment

Kerrie Patricia Westaway

Registered General Nurse – Tamworth Base Hospital, NSW
Coronary Care Certificate – Queen Elizabeth Hospital, SA
Bachelor of Health Science – University of New England, NSW
Master of Health Science with Honours – University of New England, NSW

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Abstract

The clinical effectiveness of warfarin as an anticoagulant in the primary and secondary prevention and treatment of thromboembolic disease has long been established. With the advent of anticoagulant treatment for atrial fibrillation, the number of patients receiving warfarin therapy has dramatically increased. Conversely, warfarin is a potentially hazardous drug with research indicating that patients are at the greatest risk of bleeding during the first three months of treatment and that anticoagulants have undergone the greatest increase in adverse drug reactions in Australia since 1981, revealing that this is a highly prevalent, costly process that will continue to grow in the future.

Therefore, this study investigated the current process of management of warfarin therapy through the hospital/community interface from initiation for a period of five months, or less if warfarin therapy was ceased prior to this time. It was anticipated that this study would clarify unresolved key issues of warfarin therapy during this time in order to improve clinical outcomes and consequently reduce costs.

An exploratory descriptive survey design was used to allow the collection of quantitative data from 294 men and women aged 18 years and older of all backgrounds, who had commenced on warfarin therapy in the study hospital or in General Practitioner rooms, such commencement having been brought to the attention of the researcher. The sample thus constituted a convenience sample. Quantitative data included demographic details of the patients plus information pertaining to their warfarin therapy, their health status, their level of warfarin knowledge, the degree of compliance of patients prior to an episode of over-anticoagulation and current medical trends used in the management of patients receiving warfarin therapy.

Descriptive and inferential statistical analyses of the data revealed several significant findings, the major one being that patients were found to be at the greatest risk of incurring an adverse event during the initial month of treatment. Descriptive analysis of the data revealed that overwhelmingly the majority of episodes of over-anticoagulation occurred during the initial month of treatment and became progressively less thereafter. Findings further revealed seven major bleeds occurred during the first three months of treatment while six of those bleeds occurred during the initial fifteen days. The overall level of warfarin knowledge by patients was found to be poor, indicating that the majority of patients being discharged home on warfarin therapy were not aware of the main side

effect of warfarin, and thus not knowing what signs and symptoms of bleeding to look for or when to report them to their treating doctor.

Inferential analyses of the data revealed that variables of interest such as the frequency of monitoring during the initial month of treatment, decreased oral intake, amiodarone, serum albumin, diarrhoea for at least two consecutive days, antibiotics and age were significant predictors of an episode of over-anticoagulation. Additionally, such variables as the Hospital at Home Services and normal serum albumin levels were found to act as protective factors against an episode of over-anticoagulation. Finally, when all of the significant findings of this study were collectively examined, the results clearly indicated that many of the episodes of over-anticoagulation were potentially preventable.

Whilst it is acknowledged that the ability to generalise the findings of this study is limited and no inference of causal relationships can be drawn, the results provide significant information for the re-evaluation and implementation of new strategies and policies regarding warfarin management during the initial few months of treatment, especially during the initial month. Thus, this exploratory research has identified gaps in the current system and laid the foundations for further research in the prevention of episodes of over-anticoagulation and the general management of patients receiving warfarin therapy during the initial five months of treatment.

Statement of Authentication

I certify that the substance of this thesis has not already been submitted for any degree and is not currently being submitted for any other degree or qualification.

I certify that any help received in preparing this thesis, and all sources used, have been acknowledged in this thesis.

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Abbreviations

ACCP	American College of Chest Physicians
AF	Atrial Fibrillation
AMI	Acute Myocardial Infarct
APTT	Activated Partial Thromboplastin Time
AVR	Aortic Valve Replacement
CRR	Clinical Reporting Repository
CVA	Cerebral Vascular Accident
CVD	Coronary Vascular Disease
DVT	Deep Venous Thrombosis
FFP	Fresh Frozen Plasma
GP	General Practitioner
Hb	Haemoglobin
HREC	Human Research Ethics Committee
HM	Home Monitoring
IHD	Ischaemic Heart Disease
INR	International Normalised Ratio
ISI	International Sensitivity Index
MVR	Mitral Valve Replacement
NHMRC	National Health and Medical Research Council
NPP	National Privacy Principles
NSAIDS	Non-Steroidal Anti-Inflammatory Drugs
OACIS	Open Architecture Clinical Information System
OPD	Out-Patients Department
OTC	Over The Counter
PBS	Pharmaceutical Benefits Scheme
PE	Pulmonary Embolus
POC	Point of Care
PT	Prothrombin Time
PTR	Prothrombin Time Ratio
RCPA	Royal College of Pathologists of Australia
RPBS	Repatriation Pharmaceutical Benefits Scheme

SPSS	Statistical Package for the Social Sciences
SSRI	Selective Serotonin Reuptake Inhibitors
UC	usual care
UR	Unit Record