Victorian Institute of Forensic Medicine

Residential Aged Care Communiqué

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CONTENTS

EDITORIAL

Welcome to the second issue of 2017. This edition focuses on one well-known high-risk medication, the oral anticoagulant warfarin. Similar issues appeared in cases we presented almost 10-years ago in the RAC-Communiqué December 2008. The cases included this time highlight the human factors or systemic issues around medication use and their management.

One of the cases investigated by the coroners highlights the importance of professional accountability or governance of care and communication of key clinical information. The events that led to the death of a patient recently commenced on warfarin anticoagulation demonstrate that blind faith in our systems of care is never enough, and the correct checks and balances must be put in place around the systems. When dealing with known high-risk matters we must recognise that our communication during a handover is only complete if the receiving health professional tasked with continuing care of the patient is made aware in a timely fashion of what is expected of them.

The other case in this edition brings to our attention the complex issues of what is appropriate care when an older person has a serious complication from a prescribed medication. Whether we should pursue further tests by transferring residents from RACS to an acute hospital following a fall, or opt for a more conservative approach, is always difficult. This dilemma arises when we have guidelines to follow that do not allow consideration for the individual or contextual factors. Sometimes, the exception to the rule is the correct approach.

Our expert commentary is written by A/Prof Merrole Cole-Sinclair, a Consultant Clinical and Laboratory Haematologist with enormous experience in the use and monitoring of anticoagulants.

Save the date: 'Lost and Found' Seminar

The RAC Communiqué team will be hosting another seminar in Melbourne, Victoria on Friday 24-November 2017. The seminar, titled ‘Lost and Found’ will examine the challenging and at times controversial issue of residents leaving without notification. This is sometimes referred to as absconding, escaping or elopement. Speakers will address a range of topics and Marta Woolford will present the results of her PhD research examining all deaths in Australia from 2000 onwards reported to the Coroners Court of residents who left without notification.

To encourage everyone from students to senior staff members of RACS to attend and learn more about keeping our residents safe, the registration is as low as we could make it at $165.

Places are limited. See link for save the day flyer: http://www.vifmcommuniques.org/?p=4924

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Next issue: August 2017

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Case #1 - Blind faith fails as a safety net

Case Number: (2/2015 (0051/2013) SA)
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Mrs AA was an 86-year-old female who lived alone at home and had a past medical history of paroxysmal atrial fibrillation and a remote history of colorectal cancer. In December, Mrs AA consulted a cardiologist for the results of a 24-hour Holter monitor. This investigation revealed persistent atrial fibrillation. At this consultation, aspirin was ceased and warfarin was commenced. The cardiologist wrote a script for warfarin 5mg daily and advised Mrs AA to make an appointment with her general practitioner. He also provided a pathology request for an INR test to be done in two days. This pathology request was marked as urgent and under clinical information was written 'Warfarin'.

The cardiologist counselled Mrs AA regarding warfarin safety and the importance of monitoring with blood tests. A letter was dictated to the general practitioner, whilst Mrs AA was still in the consulting room, advising of the medication changes.

Two days later, Mrs AA undertook a blood test and the INR result was 1.9. Mrs AA continued to self-administer warfarin 5mg each night as prescribed.

In January (16 days after starting warfarin), Mrs AA contacted her doctor's office stating that she was concerned about the presence of blood in her urine. Her general practitioner visited her at home that evening. At this consultation he became aware that Mrs AA had been commenced on warfarin. He performed a urinalysis which demonstrated the presence of both red and white blood cells. He advised Mrs AA to withhold her evening warfarin and commenced the antibiotic trimethoprim for a presumed urinary tract infection. As it was late in the evening, the GP decided to return the following day to perform an INR.

The following day (Friday), Mrs AA's general practitioner returned at 1:50pm. He noted that her haematuria was resolving. He performed a blood test for an INR and the pathology specimen was collected from his office later that afternoon.

The request stated 'On warfarin' and did not reference Mrs AA's ongoing haematuria. The pathology sample was not tested at the pathology lab as the tube was underfilled.

Multiple attempts by the laboratory to contact the general practitioner to advise him of this were unsuccessful.

On Saturday morning, Mrs AA contacted her son to tell him she had fallen the previous evening and struck her head on the end of her bed. Her attempts to contact her GP were unsuccessful as the clinic was unattended. She then contacted a 24-hour medical advice service. Mrs AA explained to the operator that she had recently commenced warfarin, had blood in her urine, had fallen knocking her head the previous evening and now had a 'dull head' and arm bruises. Mrs AA was counselled to call 000 if she experienced any further symptoms such as headache, drowsiness or vomiting.

That afternoon her son and daughter-in-law found Mrs AA at home and unresponsive. Mrs AA was transported by ambulance to hospital where blood tests revealed an INR = 12. Mrs AA died that evening.

> The coroner found that the cardiologist's failure to contact the GP to inform him about the introduction of warfarin was an unsafe practice.

Pathology

The cause of death following an autopsy by a forensic pathologist was a right subdural haematoma due to blunt head trauma with contributing warfarin anticoagulation. Post-mortem examination revealed widespread evidence of over-anticoagulation, with subarachnoid, renal pelvicalyceal and mediastinal haemorrhages.

Investigation

An Inquest was held and required five days in court over five months. There was an extensive investigation with statements and evidence taken from the cardiologist, general practitioner, pathology service and medical expert, amongst others.

The coroner found that the cardiologist's failure to contact the GP to inform him about the introduction of warfarin was an unsafe practice.

The coroner noted that the letter dictated to the GP would not reach the general practitioner for 21 days and that the GP's details were not added to the initial pathology request.

The coroner also noted that direct methods of communication with the GP such as a simple phone call, email or fax, were more appropriate. Further, if the GP's details had been provided on the pathology slip this would have alerted him to follow up on the results.

The cardiologist's reliance on Mrs AA to initiate the contact with her GP was inappropriate. Alternatively, the cardiologist could have requested the GP himself to initiate warfarin therapy.

> The GP failed to mark it as urgent or include the clinical concerns about bleeding and unmonitored warfarin therapy on the pathology request.

Mrs AA's GP only became aware of the use of warfarin when she eventually initiated a review for haematuria. At this consultation, it appears that Mrs AA's GP did not appreciate the significance of the inadequate warfarin monitoring or her risk of a catastrophic bleed. He did not suggest at any point that Mrs AA required hospitalisation.

He performed an INR blood test the following day, however the laboratory treated the sample as a routine test for INR. This is because the GP failed to mark it as urgent or include the clinical concerns about bleeding and unmonitored warfarin therapy on the pathology request.

The pathology company provided evidence that if the importance of the blood test had been imparted to them, they may have been able to perform an analysis on a slightly underfilled sample. Critically high INR levels may even be reported to police if the doctor or patient cannot be contacted. The GP did not follow up the results of the INR test he performed, and gave evidence that it had slipped his mind. These two medical reviews represented missed opportunities for Mrs AA's bleeding risk to be evaluated, and possibly have her warfarin reversed.

Finally, the prescription of an antibiotic was also considered by the coroner, as trimethoprim may potentiate the anticoagulant effects of warfarin. Whilst the use of trimethoprim was deemed inappropriate (as Mrs AA's main clinical concern was her bleeding not a urinary tract infection) it was not felt to have contributed to her elevated INR as this effect can take 5 days.

Coroner's Comments and Findings

The coroner formed the view that appropriate monitoring of INR or timely attempts to establish her INR when she presented with haematuria could have prevented Mrs AA's death.

> The coroner found that the cardiologist's failure to contact the GP to inform him about the introduction of warfarin was an unsafe practice.

The coroner recommended that specialist medical practitioners do not undertake the prescribing of warfarin themselves; rather it would be appropriate for the GP to both initiate and monitor the warfarin.

The patient should not be burdened with the responsibility of informing their usual doctors about the commencement of warfarin.

If a specialist does prescribe warfarin but does not intend to monitor blood levels, communication with the treating GP should be timely - in the form of a telephone call, fax or email. The GP should be copied into the results of any INR pathology requests.

Finally, the coroner recommended that all medical practitioners include all significant clinical information on INR request forms, including information about inadequate INR monitoring if relevant.

Case #2 - CT or NOT to CT

Case Number: 2011/0526 SA Inquest number 5/2014

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Mrs MF was an 84 year old female with dementia, heart failure, atrial fibrillation, deep venous thrombosis with pulmonary emboli and macular degeneration. Prescribed medication included warfarin because of past thromboembolism and stroke risk from atrial fibrillation, and risperidone for agitation.

Mrs MF resided in an aged care facility where she required full nursing care due to visual impairment, confusion with agitated behaviour and physical dependency. Although she was unable to walk and required a hydraulic lifting device to move to her recliner chair, she would try to stand and was considered a high falls risk.

During the day, Mrs MF's princess chair was located close to the nurses' station to allow close observation.

One day, Mrs MF had an unwitnessed fall from her chair and was promptly assessed by nursing staff. They commenced neurological observations and notified the family and the GP. Nursing staff had difficulty obtaining cooperation for the neurological observations but Mrs MF denied having a headache and was able to ask for a glass of water later that afternoon.

Overnight there were no further neurological observations. Eventually, Mrs MF was transferred to a large metropolitan acute care hospital where an acute left sided subdural haemorrhage was diagnosed. Mrs MF died soon after.

Pathology

A forensic pathologist confirmed the cause of death was an acute left subdural haematoma.

Investigation

An inquest was held and required four days in court over nine months and the coroner requested an expert opinion from a medical specialist in geriatric medicine. The expert opined that the anticoagulant therapy was appropriately monitored by the GP, and that antipsychotic medication may have added to Mrs MF's impaired balance and falls risk.

Mrs MF was at increased risk of traumatic subdural haematoma due to the use of anticoagulant medication. Also, the cerebral shrinkage that occurs in older persons may lead to later onset of symptoms and/or altered conscious state due to the increased space within the skull.

> Patients with a minor head injury who are on anticoagulant medication should have a CT head scan to rule out inracranial bleeding.

Additionally the following questions were raised: What should be the appropriate response to a fall with minor head injury in a frail nursing home resident? In particular, what is the role of CT scanning in patients with a minor head injury who do not appear to have any obvious deterioration in mental state? And lastly, what difference in response should occur with patients who are prescribed anticoagulation therapy?

The expert summarised his view by saying that patients with a minor head injury who are on anticoagulant medication should have a CT head scan to rule out intracranial bleeding, excluding those where there is a clear advance care directive or palliative care plan such as they did not wish for intervention or hospitalization.

The coroner also noted that the reason for a lack of overnight clinical observation of Mrs MF by an agency nurse was not up to an acceptable standard. The explanation of not wanting to disturb Mrs MF's sleep was not acceptable or deemed to be in the resident's best interests.

Coroner's Comments and Findings

The Coroner did not find that care in the RACF was lacking but considered this was an opportunity to make recommendations about whether residents in RACF should be sent to hospital for assessment and CT head scanning after minor falls with head strikes, especially when on anticoagulant medication.

> Falls in aged care facilities and hospitals remain the single highest adverse event and protocols to provide appropriate and evidence based care are required.

Subsequently, the coroner recommended that the State Ministers for Health and Ageing, and the Commonwealth Minister for Health and Aged Care consider adoption of a protocol under which RACS facilities would refer patient following falls resulting in minor head injuries to hospital for assessment, and that hospitals receiving such patients should give consideration to carrying out of a CT scan for at least those patients who are on anticoagulation therapy.

Author Comments

Falls in aged care facilities and hospitals remain the single highest adverse event and protocols to provide appropriate and evidence based care are required. In high risk patients, the risk and benefit of continuing anticoagulant therapy and an agreed action plan where a predictable side effect occurs should be documented in advance.

> Advance care planning is a crucial component of providing optimal care for older patients with life limiting conditions admitted to RACS.

The burden and distress to a resistive resident or patient being transferred to hospital for a potentially long period of assessment followed by a CT scan under restraint or sedation needs to be weighed against the benefit of such an action and indeed whether a neurosurgical procedure would be either wanted, safe or effective.

Advance care planning is a crucial component of providing optimal care for older patients with life limiting conditions admitted to RACS.

Keywords

Anticoagulant therapy, Residential Aged Care, Subdural Haemorrhage, Advance Care Plan

Clinical Commentary - The key to warfarin efficacy and safety

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Initiation of any new therapy for a patient requires the treating doctor to establish an accurate diagnosis and/or appropriate indication for the treatment and then correctly prescribe the treatment. If this is a drug they must also be aware of, and engage the patient/carer in a discussion of the benefits and risks of the proposed therapy (including medication monitoring/interactions), and advise them (and their GP), any requirements for regular clinical assessment, monitoring and adverse event reporting.

Initiation of anticoagulation (AC) with the oral anticoagulant (OA) medication warfarin (which is a vitamin K antagonist), is an example where all of these requirements are absolutely crucial to ensuring ongoing therapeutic benefit and minimisation of harm, especially from a serious bleeding complication such as intracranial bleeding (which is a major cause of morbidity and mortality, as illustrated by these cases). Minor or major bleeding can occur in patients well controlled in the therapeutic INR range on warfarin, however the bleeding risk increases as the INR becomes significantly elevated above the therapeutic range.

The patient/carer/doctor must be aware with any OA including warfarin that these agents can significantly potentiate bleeding due to trauma.

Whilst there is evidence that some bleeding risk may be reduced with the 'new' direct acting OA drugs (DOACS) in certain circumstances compared with warfarin, some especially older patients are not suitable to commence a DOAC, and warfarin remains in widespread use for stroke prevention in non-valvular AF and therapy for/prevention of VTE, with well-established therapeutic INR ranges and guidelines for AC management and associated risk mitigation strategies (see resources *Tadros* and *Shakib*).

The patient/carer/doctor must be aware with any OA including warfarin that these agents can significantly potentiate bleeding due to trauma such as head strike, back or soft tissue injury, fracture etc., as seen in the case of Mrs MF.

Patients must be provided at the time of initiation of warfarin AC with tablet sizes allowing variation of dose to within half-one mg, and with written drug information and instructions as to INR monitoring arrangements, which should be frequent in the initial period of stabilisation.

Whilst many patients are vigilant about reporting overt bleeding events such as epistaxis, bleeding may be concealed, such as intracranial or retroperitoneal, or initially concealed such as with upper GI haemorrhage, so that new onset headache, back/groin pain or dizziness/faintness may be the presenting symptom of covert serious bleeding. These possible diagnoses should be considered in any clinical assessment of patients on ACs with a history of even relatively minor trauma or new onset of relevant symptoms.

Patients must be provided at the time of initiation of warfarin AC with tablet sizes allowing variation of dose to within half-one mg, and with written drug information and instructions as to INR monitoring arrangements, which should be frequent in the initial period of stabilisation. Pharmacists often provide valuable initial and ongoing OA patient education.

Warfarin inhibits the Vitamin K epoxide reductase complex and therefore the activity of a number of procoagulants and to a lesser extent anticoagulant proteins. Its potential dose range is very wide and the therapeutic dose is affected by several factors. These include: (a) diet [varying oral Vitamin K intake]; (b) intercurrent illness; (c) many interacting medications [especially antibiotics and including complementary medicines]; (d) disease states such as thyroid, liver and cardiac disorders and; (e) alcohol intake. Concurrent use of other drugs associated with haemostatic compromise e.g. aspirin, NSAIDs etc. also compound the bleeding risk.

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FEEDBACK

The editorial team is keen to receive feedback about this communication especially in relation to changes in clinical practice. Please email your comments, questions and suggestions to:
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The therapeutic effect of warfarin, i.e. the INR, must therefore be monitored regularly and patients/carers well educated about these potential interactions. Any change in medication or dose, especially with highly protein-bound drugs, may significantly alter a previously stable warfarin dose so it is important to ensure early INR checks in these circumstances to avoid inappropriately high or low INRs.

OAs are prescribed/recommended by doctors in several disciplines including cardiology, haematology, respiratory and general medicine, GPs and others, initially in hospital or ambulatory settings. Responsibility for overseeing ongoing management of OA usually lies with the GP and, depending on the jurisdiction and practitioner preference, the actual dosing of warfarin is performed by the GP, a pathology service or a specialist.

The key to warfarin efficacy and safety, and minimisation of associated bleeding risk is timely and accurate stakeholder communication and documentation.

In certain situations, even the patient may monitor the warfarin dosing to some extent, if they use an appropriate point of care INR device under medical supervision.

Temporary interruption of OA for procedures/hospitalisation/high INR/bleeding etc. often also necessitates involvement of emergency/other hospital medical personnel including perioperative/surgical/hospital at home staff etc., compounding the challenge of appropriate AC advice handover.

The key to warfarin efficacy and safety, and minimisation of associated bleeding risk is timely and accurate stakeholder communication and documentation, the central of these being the patient and/or their carer/s and their GP.

At any given time an individual medical practitioner must be accountable for managing a patient's warfarin AC and ensure accurate, sufficient and timely handover when this responsibility transfers to another doctor, including those delegated to provide dosing advice to the patient at a pathology service.

Failure to do so, as in the case of Mrs AA, can lead to inappropriately high INRs with the attendant potentially fatal bleeding risk, or low INRs with thromboembolic risk. Failure to closely monitor INRs when there is relevant medication change, as seen in the case of Mrs AA, can potentiate these risks.

A simple explainer of the international normalized ratio (INR)

The INR is a laboratory test that is used to monitor whether anticoagulant medication such as warfarin is having the desired effect on the body's clotting system. A normal value for a person not on warfarin is an INR<1.1. The therapeutic range varies depending on the condition being treated and is typically an INR between 2.0-4.0. The risk of bleeding as a complication is greater as the INR increases, especially with older people.

List of resources

1. *Tadros and Shakib, Australian Family Physician vol 39 [7] July 2010; Anticoagulants: a guide to starting oral anticoagulation in atrial fibrillation, NPS MedicineWise.*

2. Tran HA, Chunilal SD, Harper PL, Tran H, Wood EM, Gallus AS. An update of consensus guidelines for warfarin reversal. MJA 2013;198(4):198–199. - See more at: https://www.transfusion.com.au/disease_therapeutics/warfarin/guidelines_warfarin_reversal#sthash.1kdpvdly.dpuf

3. Australian Red Cross Guidelines for the management of an elevated INR in adults available at: https://www.transfusion.com.au/disease_therapeutics/warfarin/guidelines_warfarin_reversal

4. RAC-Communique Vol 3 Iss 5 December 2008. This explored three other cases involving warfarin. It also highlights systems issues about effective communication and co-ordination of care between clinicians, laboratory services, patients and their family.