Original Scientific Paper

Therapeutic monitoring of warfarin

– an audit of monitoring protocols and outcomes

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ABSTRACT

Anticoagulants have proven benefit in the primary and secondary prevention of thromboembolic disease.[1] Warfarin, the most commonly used anticoagulant was studied. Bleeding is the major side effect of warfarin and is a major deterrent to its use, especially in older patients.

Physicians at Hutt Hospital requested identification of warfarin monitoring protocols and expressed concern that some patients were not being adequately monitored. General practitioners (GPs) have requested remuneration for monitoring and managing anticoagulation. A summer student project aimed to ascertain the prevalence of warfarin patients, the monitoring methods of warfarin in each practice and the incidence of major adverse bleeding.

The audit results show that the method of warfarin monitoring is similar over the eight practices surveyed. However there were differences in the rigour applied to the management of non-attendees. There was no evidence that major adverse bleeding events were more frequent than published international data. Some questions arose in regards to the quality of the current monitoring processes that require further research.

And finally a cost formula for warfarin monitoring was developed.

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Introduction

Bleeding is a serious complication of anticoagulant treatment. Anticoagulants are the second most common drug group reported as causing an adverse drug reaction associated with hospitalisation.[2] In treating the patient with anticoagulants the key question is whether the benefit of the treatment outweighs the risk of bleeding.

Warfarin has a narrow therapeutic index and close monitoring is important. Prothrombin times are generated each time a patient on warfarin has a blood coagulation test. Reporting prothrombin times as an international normalised ratio (INR) eliminates interlaboratory differences and hence increases reliability.[3,4] The therapeutic range of INR for most patients lies between 2.0–3.0. For patients with heart valve replacements the therapeutic range is 3.0–3.5. With values of INR above or below the therapeutic range, the patient runs the risk of being inadequately anticoagulated or being predisposed to bleeding.

There is a higher incidence of bleeding in patients who are more intensely anticoagulated.[5] The most common sites for anticoagulant related bleeding are the gastrointestinal tract, the urinary tract, the soft tissues and the oropharynx. In the general practice setting nose bleeds are a very common presentation. Intracranial bleeding is a rare but dreaded side-effect and accounts for the most deaths. The average risk for major bleeding with warfarin is around 3–5% per year; this range is derived from international studies.[6,7,8]

Physicians working at Hutt Hospital were concerned by a perceived increase in warfarin-related bleeding. As a result of a sentinel event the physicians wanted reassurance that there was adequate post-discharge follow-up of warfarin patients. In addition to the physicians' concerns, increasing demand placed on general practitioners by warfarin monitoring led to a request for explicit funding from the Hutt Valley District Health Board (HVDHB). These two requests prompted an audit of the warfarin monitoring protocols in the Hutt Valley.

Three steps were undertaken.

- A review of bleeding events at Hutt Hospital coded under ICD 10 was undertaken.
- A sample of general practices in the Hutt Valley was surveyed.
- A cost analysis was made.

Method

Initially an electronic search of the hospital patient management system for the period of 2001–2003 was undertaken to identify any cases that were coded under ICD 10, with anticoagulant related bleeding as a primary diagnosis. This strategy found only a small number of cases. A further random audit of 50 patients who were admitted to Hutt Hospital with an INR greater than seven was undertaken.

The second part of the project involved talking to general practitioners and nurses from various practices in the Hutt Valley. Eight practices were selected to partake in the survey. A conscientious effort was made to select practices that would be representative of the diverse practice sizes, patient socioeconomic status and age distributions of the various practice settings in the Hutt Valley area. A formal questionnaire was developed to ensure that the same information was gathered from each practice. Questionnaire topics included: total number of patients in the practice, number of warfarin patients, INR monitoring protocol, time constraints of warfarin monitoring and site of warfarin commencement (Hospital or GP). Using telephone surveys or visits, information was then gathered from the doctors and nurses who monitored the INR results. Cost analysis was then undertaken on the tabulated data.

Findings

The GP survey covered a population of 66 869 out of a total population of 137 000 in the Hutt Valley region.[9] The largest practice had a patient population of 17 400 and the smallest practice had a patient population of 1700. In total the audit covered eight general practices. The prevalence of patients taking warfarin in the practices studied ranged from 0.40–0.94% with an average prevalence of 0.57%, a total of 381/66 869. If this prevalence value is extrapolated for the total DHB population of 137 000 then there are 780 warfarin patients in the region.

The findings from the survey show that monitoring protocols for warfarin across the region are very similar. An outline of a typical monitoring protocol is as follows: initially the patient has a blood test and an INR value is obtained. This value is then forwarded to the practice nurse by the laboratory. The nurse consults the doctor regarding the INR value, and determines if any alteration should be made in the dosage of warfarin. Once the dosage is decided the nurse contacts the patients by telephone and conveys any necessary changes. Patients who are starting on warfarin are monitored at intervals at the discretion of the GP, usually once every few days. Once the INR is stable they are monitored every four to six weeks. The key issue is that, despite similar monitoring methods there may be differences in the consistency of the INR monitoring and warfarin dosing. In some practices non-attendees are actively followed up while in others they are not.

An attempt was made to quantify the number of hours spent by a nurse and a doctor on warfarin monitoring per patient per year. Some small practices had difficulty stating how long each nurse or doctor spent on monitoring. The recorded results produced an average value of 3.2 hr/yr per patient for nurses and an average value of 1.5 hr/yr per patient for doctors. These figures can be used to derive some values for funding purposes. The cost of a nurse was calculated at $50/hr; therefore the total cost per year in the Hutt Valley for nurse time would be $124,800. The cost of a doctor was calculated at $200/hr and a value of $234,000 obtained. Thus it would cost Hutt Valley DHB $460 per patient per

Table 1. Demographics and monitoring protocols of patients on warfarin at various general practices

Total number of patients in practice	Number of Doctors	Number of patients on warfarin	Prevalence of warfarin patients	Monitoring period – stable patients	Nurse time: hr/yr/patient	Doctor time: hr/yr/patient	Opinion on warfarin monitoring
1700	1	16	0.94%	6–8 weekly	3.25	1.62	Clinic based best
2743	1	11	0.40%	monthly			Practice based best
3000	2	16	0.53%	monthly			Practice based best
3000	2	14	0.46%	monthly	3.71	0.92	Practice or Clinic
8000	2 Full Time, 4 Part Time	49	0.61%	6 weekly	2.65	1.33	Practice based best
14 000	5	67	0.48%	monthly	1.94	0.19	Practice based best
17 026	10 Full Time	106	0.62%	2,4,6 weekly	4.09		Practice based best
17 400	7 Full Time, 4 Locums	102	0.58%	fortnightly or monthly	3.82	3.57	Practice based best

annum to fully fund the costs of practice-based monitoring – a total of $358,000 per annum.

The review of the ICD 10 coded anticoagulant bleeding inpatient events at Hutt Hospital yielded eight patients. All of these patients were on warfarin. The events all occurred in the last year (2003), despite the review period being from 2001–2003. Given that eight major bleeding events out of our estimated warfarin patient population of 780 indicates a frequency of 1% (significantly lower than international figures), this figure should be viewed with caution. This suggests that some of the earlier bleeds were not coded or coded incorrectly and hence did not show in this search. A subjective view of the list by hospital physicians indicated this list was not complete.

Discussion

The total number of elderly patients in New Zealand is increasing. With increasing age the prevalence of atrial fibrillation also increases. Atrial fibrillation is the major indication for warfarin therapy.[10] With the ever increasing use of anticoagulation, thorough monitoring of INR will become more time consuming. This study attempted to identify the prevalence of adverse reactions to anticoagulants, best monitoring practices and cost analysis for funding.

From our study we were able to ascertain that monitoring methods varied from one practice to another. Three of the larger practices were capitated and therefore could choose to dedicate resources to the monitoring process. Smaller and solo practices depend on the practising doctor to invest time in monitoring. When the individual practices were asked which form of warfarin monitoring they preferred (practice-based vs hospital clinic), the majority preferred a practice-based approach. GPs often see patients for a number of unrelated events or medical conditions, and hence have more contact with them than the hospital. A practice-based monitoring system is consistent with this holistic approach to patient management. The other advantage of a practice-based monitoring system is that the practice doctor is better acquainted with the past medical history of the patient. The main reason why the minority of the surveyed GPs preferred a clinic-based approach was because it relieves the practice doctor of the responsibility and time of warfarin monitoring.

Practices who were surveyed mentioned that most of their patients were started on warfarin at the hospital. This raises the question of whose responsibility it is to educate the patient. Certain practices use nurses to educate the patient about warfarin once they have been referred from the hospital. Because of the drug's adverse side effects, thorough education of the patient and confirmation that they understand the principles behind the ongoing treatment is essential. Are the doctors at the hospital responsible for the education because they were at the point of initiation of the treatment, or does the responsibility fall upon the GP who will monitor the patient thenceforth? Either way there seem to be some differences between the various practices as to who currently provides patient education. Patient compliance is subject to a number of factors including understanding of the need for warfarin, having a fixed address and access to a telephone. Patient understanding of the monitoring process is one factor where improvements might be achieved through better patient education. This supports compliance, which is necessary with warfarin because of the need for regular blood testing.

Conclusion

Our findings on the number of hospitalisations consequent upon poor control of anticoagulation were inconclusive. There was no indication that the major adverse bleed rate was higher than published international rates. Fully funding practice-based warfarin monitoring would cost $460 per patient per annum, a regional total of $358,000. A number of recommendations have been made as a result of this study. These include:

- development of standardised patient education process
- development of standardised monitoring protocols for general practice
- improved coding of major adverse bleeds within the hospital
- consideration of funding for practice-based monitoring.

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