Audit of anticoagulant therapy

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Introduction

Anticoagulant management represents an ever increasing workload for clinicians and the laboratory service. It is important that all aspects of clinical and laboratory tests are carefully monitored through current quality assurance schemes and clinical audit. Changes in the indications for anticoagulation have resulted in a progressive increase in patients requiring lifelong oral anticoagulant therapy. This increase is mainly a consequence of patients with atrial fibrillation and underlying cardiac problems requiring anticoagulation. As treatment is lifelong the effect on the number of visits to the outpatient clinic is cumulative.

In South Warwickshire there has been a 120% increase in the number of monthly visits to the anticoagulation clinic by patients with atrial fibrillation between 1990 and 1994. Results of a follow up Regional Audit of Anticoagulants in the West Midlands, April 1992 to March 1993, showed that of patients attending anticoagulant clinics, 21% have atrial fibrillation as the primary diagnosis. In 1995 this represents the commonest indication for anticoagulation in the UK. With patient attendances more than doubling in most anticoagulant clinics in the past five years, audit of the anticoagulant service has become imperative.

The underlying principle of anticoagulant therapy is to reduce the risk of thromboembolic disease while minimising the risk of haemorrhagic complications secondary to treatment at the same time. Data collection on anticoagulant control has been greatly facilitated in recent years by clinical audit and computerisation of anticoagulant management in many hospitals.^{1,2} There is a need to monitor the standards of anticoagulation achieved and the quality of service delivered. This information may then also be used in conjunction with medical research to review the clinical indications and levels of anticoagulation required.

Audit of the quality of service from the patients' perspective also requires consideration, particularly in deciding how and where the service is to be delivered. A further aim of audit should be to minimise the risk

of untoward events relating to anticoagulant therapy. Litigation for over-anticoagulation is an obvious concern to all. However, increasing litigation associated with under-anticoagulation in North America is an equal concern.

The purpose of this review is to consider how both audit of inpatient and outpatient anticoagulant therapy can be implemented, and to identify areas where improvement in the current service can be achieved.

How well is current oral anticoagulant practice carried out?

A recent audit of anticoagulant treatment in the West Midlands measured the achievement of keeping patients within target international normalised ratio (INR) ranges by grouping patients with an INR range of 2.0-3.0 and those with a range of 3.0-4.5. Results from 10 district hospitals are presented in table 1. These results show no improvement compared with those reported from previous audits³ on hospital based anticoagulant services. Furthermore, the results are no better than those documented in a recent report where general practitioners routinely monitored anticoagulant dosage.⁴ Results for achievement of target INR ranges, however, can be improved using computer assisted dosages where the therapeutic ranges are set to comply with the British Committee for Standards in Haematology (BCSH) guidelines.⁵ Results from five district general hospitals (fig 1) show progressive improvement in terms of achievement of target INR ranges using the anticoagulant management support system. While initial improvement following implementation of the computer system could result from greater awareness and attention to the service, the prolonged improvement results from standardisation of dosage and patient recall.

An analysis of the frequency of attendance, duration of treatment and number of visits falling in range was performed on three of the more frequent indications for anticoagulation (table 2). These were deep vein thrombosis (DVT; short term anticoagulation), and atrial fibrillation and prosthetic valve replacement

Table 1 Results of audit of anticoagulant treatment in 10 district hospitals: comparison with a computer assisted clinic

	District hospital (n = 10)		Computer assisted clinic	
	Target INR range			
	2.0–3.0	3.0–4.5	2.0–3.0	3.0–4.5
Number of patient visits	11 724	9295	3525	2887
INR below minimum	17.5%	50.4%	22.5%	22.7%
INR in range	54.8%	42.9%	62%	63.7%
INR above maximum	27.7%	6.6%	15.5%	13.6%

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Figure 1 Results from five centres from initiation of computer assisted dosage, showing progressive improvement in the percentage of patients within target BCSH anticoagulant ranges over time.

(lifelong anticoagulation). Results from 79 patients in the West Midlands with DVT on warfarin showed that the range of duration of treatment varied from two weeks to nine months, with a mean duration of 2.8 months. The range of frequency of attendance was once a week to once every five weeks, with a mean frequency of 1.9 weeks. At the first visit to the outpatient clinic, 17% of patients had INR results greater than 3.0, with 69% falling in range and 14% below. Only one patient was considered to have a dangerously high INR of 6.8 at the first visit.

The average frequency of recall for 235 patients with atrial fibrillation was 42 days (range 18–91 days), while 498 patients with mechanical prosthetic valve replacements were reviewed, on average, every 38 days (range 18–73 days). The more frequent recall of patients with DVT may have resulted in a better mean percentage of visits per patient in range. However, the frequency of recall did not account for the better results observed in anticoagulant control for patients with atrial fibrillation compared with those with replacement prosthetic valves.

Results for all patients in the higher INR range of 3.0–4.5 were worse than for those

patients maintained within the lower range of 2.0–3.0.

Methods to assess anticoagulant control have focused on results falling above, below or within therapeutic ranges. Other parameters used include the time taken to achieve a target range on the percentage of patients achieving therapeutic concentrations within 24 hours. A more discrete measure reported recently is the time spent in range or the percentage of time in range for the individual patient. Similar measurements are incorporated into audit programmes used in computer assisted dosage systems.

Risk management and anticoagulant treatment

Risk management is defined as the prevention, identification, assessment, corrective action, and loss control related to occurrences that are untoward and potentially could be compensated for. This is particularly applicable to anticoagulant treatment where potential problems with treatment need to be minimised. Many different clinicians may be involved with both inpatient anticoagulation management and subsequent outpatient care. Transfer of information is often inadequate and important information may not be disseminated to all parties involved in management—for example, the clinician involved in the outpatient management of a patient on warfarin treatment might not be informed that the patient had been admitted with a gastrointestinal bleed.

A risk management strategy should include measures for risk prevention, risk identification and corrective actions. Risk prevention focuses on education of hospital staff involved in inpatient and outpatient management of anticoagulant treatment (or induction courses for new junior hospital staff). Guidelines for both inpatient and outpatient management of anticoagulant treatment are recommended. Risk identification needs a system of reporting untoward incidents pertaining to anticoagulation. This may be part of a general hospital reporting system. Assessment of current practice can be undertaken by identifying and quantifying common problems that can arise. Common errors include a delay in receipt of referral forms from hospital clinicians or referral from other centres, the failure to provide adequate information for initial assessment, failure to indicate the correct reason for anticoagulation, and duration of treatment and inadequate anticoagulant control on discharge. It is also important to define at which point clinical responsibility for outpatient management is transferred from the inpatient service.

It is recommended that clinical responsibility should commence from the time of the initial outpatient review. Examples of areas for risk monitoring and audit are outlined.

HEPARIN TREATMENT

Risk of heparin over/under anticoagulation may be reduced with attention to the following considerations for audit:

Table 2 Analysis of the frequency of attendance, duration of treatment and number of visits falling in range for three of the more frequent indications for anticoagulation

Indication	Mean % of visits per patient in range	Mean % of visits per patient above range	Mean % of visits per patient below range
DVT (2.0–3.0)	63.5%	12.5%	24%
Atrial fibrillation (2.0–3.0)	64%	25%	11%
Prosthetic valve replacement (3.0–4.5)	48%	7%	43%

- Heparin therapy should not be prescribed for more than 24 hours.
- Measurement of the activated partial thromboplastin time (APTT) on a daily basis as a minimum requirement for all inpatients receiving intravenous heparin.
- Prescribing heparin as an hourly infusion rate in preference to a dose made up for 12/24 hour infusions. This should avoid prolonged delay in reconstitution of heparin infusion.
- Infusion pumps used for heparin therapy should be monitored to observe the accuracy of the infusion rate.

WARFARIN

- Define minimum data requirement on transfer—for example, referral forms for outpatient anticoagulation.
- Provide patients with anticoagulant cards detailing nature of treatment—for example, a DHSS card.
- Audit information given to new patients—for example, do they know why they are on anticoagulants. This can be done using a simple questionnaire at the initial visit.
- Ensure hospital notes contain information that a patient is on warfarin.
- Use of established warfarin/heparin dosage schedules in the hospital setting.
- Ensure that the diagnosis and duration of anticoagulation is known for all patients.
- Can patients who have missed outpatient appointments by more than four weeks be identified?

Where risk assessments identify needs for corrective action this information needs to be relayed to all relevant clinical personnel and incorporated into new guidelines.

Audit of start of anticoagulant therapy

Audit of management of anticoagulation is best carried out where there are standard charts for anticoagulant therapy used routinely on wards. Simple algorithms for commencement of heparin and warfarin therapy can be incorporated into the chart.⁷

Areas for consideration of audit would include the duration of inpatient heparin therapy for DVT/PE and the level of anticoagulation achieved as measured by the APTT and the INR. In 75 patients treated locally with intravenous heparin the duration of treatment ranged from two to 19 days (mean six days). The time interval between starting heparin and warfarin therapy ranged from zero to 16 days. Since the introduction of an anticoagulant dosage schedule the duration before commencement of warfarin therapy has reduced to less than 72 hours.

Tan *et al*⁸ reported that the crossover period between warfarin and heparin treatment is particularly difficult. In an audit of 100 case notes they reported that 33% of APTT results and 58% of INR results were not therapeutic, while 37% of patients stopped heparin therapy when the INR was subtherapeutic.

With increasing demands for hospital beds, audit should ensure patients are discharged promptly, but not prematurely, and with stable INR values.

Audit of anticoagulant prophylaxis

The audit of anticoagulant prophylaxis is a difficult undertaking, requiring considerable time to access information from different sources. There may be, however, considerable resource and financial benefit in the long term. The sample population can be obtained by identifying patients with ICD codes for DVT and PE through the hospital patient administration system. This should include cases with other primary diagnoses at admission, developing thromboembolic complications while inpatients. To identify patients developing thrombotic events after discharge is more difficult. Information on readmissions within three months including high risk post-operative cases can be audited.

Of 105 patients with DVT/PE audited recently, 30 had undergone a surgical procedure within three months of admission, four of whom died. Five of the 30 patients were given prophylactic anticoagulant treatment with low dose standard subcutaneous heparin for five to eight days. The thromboembolic event was diagnosed in seven of the 30 patients during the postoperative inpatient stay. The 23 patients who developed a thromboembolic event after discharge following surgery were readmitted within five to 52 days (mean 24 days), with a total additional hospital inpatient stay amounting to 243 days.

In the present climate of restricted finances, a pragmatic approach to prophylactic anticoagulation may be cost-effective. The outcome of this audit was to reassess the thrombosis risk score sheet, where patients with four or more risk factors were given prophylactic heparin, and to extend the indications to other orthopaedic surgical procedures. In these clinical groups low molecular weight heparin therapy is now routinely used in preference to standard low dose heparin.

The quality of anticoagulant service

A patient's concept of quality of service can be monitored using standard hospital quality criteria. Anticoagulant clinics suffer by virtue of the number of patients attending and the frequency of recall. A patient's view of quality of service may focus on the size of the hospital car park, and the time taken for review. Therefore, efforts to decentralise large clinics and provide local near patient testing and dosing are worthy of evaluation. Recently, small oral anticoagulant analysers have become available for near patient testing,⁹ with capillary blood sample analysis, simple handling and immediate availability of results from one drop of blood. However, with near patient testing there is still an important need for hospitals to provide and ensure access to appropriate quality assurance schemes, with guidelines to local services—for example, general practices un-

Figure 2 Results from five centres using computer assisted dosage of anticoagulation, showing percentage bleeds and INR values.

undertaking the control. Audit of evaluation of patients' knowledge of anticoagulant treatment may be more important in this setting. Check lists for patient counselling may be used, with reinforcement of advice by non-medical personnel. A recent report¹⁰ suggested few patients could correctly identify adverse factors associated with poor control. Only 60% identified bleeding, 36% thrombosis and 52% excessive alcohol consumption as possible indicators of poor control.

Audit of excessive oral anticoagulation

Audit information can be pooled from different centres to evaluate INR values for haemorrhagic risk while on warfarin therapy. Collection of computer data from five hospitals, from 43 788 visits by 4277 patients is shown in fig 2. In total 885 bleeding events were recorded (table 3). Differences in the rate of reporting haemorrhagic episodes were noted from the different centres. This reflects the diligence of those involved in recording such events. There is also a grey clinical area, as to what is and what is not a significant bleeding event. Significant findings can, however, be extracted from this type of large volume data.

Table 3 Percentage of total bleeds and reasons for haemorrhage in 885 patients undergoing warfarin therapy

Problem	n	Percentage of total bleeds
Excessive bruising	311	35
Epistaxis	266	30
Oral mucosal bleeding	82	9
Haematuria	78	9
Gastrointestinal bleeding	31	4
Menorrhagia	30	3
Haemoptysis	13	2
Others	74	8

The results from all five centres showed a consistent increase in bleeding events for INR values greater than 5.0. For all INR results of less than 4.9, 1.6% bleeding events per visit were recorded, compared with 10.2% bleeding events per visit with INR results greater than 5.0. It is interesting that no significant difference in bleeding events was observed for the two commonly used INR ranges of 2.0-3.0 and 3.0-4.5. The use of this type of large volume audit data is helpful and can complement that obtained from clinical research trials where much smaller numbers of patients are more rigorously monitored.

Other methods for auditing excessive oral anticoagulant therapy may focus on patients with high risk bleeding events or patients grossly over-anticoagulated. Examples of audits undertaken include patients with INR values greater than 8.0,¹¹ or the use of therapeutic interventions to reverse the effects of warfarin with fresh frozen plasma/coagulation concentrates. A recent audit of 2526 outpatients identified 1.8% (45) of patients with INR values greater than 8.0 over a 12 month period.

Audit of medical records from these patients showed that reversal of over-anticoagulation using the BCSH guidelines was not complied with for 61% of cases, and in seven cases this was potentially hazardous. Concurrent infection, disseminated intravascular coagulation, other drug interactions, and the presence of liver disease were identified as major risk factors in this group of over-anticoagulated patients. Furthermore, the mean patient age of the over-anticoagulated patients was significantly higher at 70 years than that of the overall group at 57 years. Several reports^{12,13} have now clearly documented that clinicians need to be particularly careful when initiating warfarin therapy in elderly patients. Hospital policies for anticoagulation need to incorporate reduced loading doses for patients over the age of 70 years starting warfarin therapy.

While the establishment of audit programmes may involve an initial increase in workload, the long term benefits may result in better inpatient and outpatient control, using less qualified staff. For example, the use of routine inpatient treatment charts is beneficial to all grades of staff involved in anticoagulant monitoring. Furthermore, the decentralisation of anticoagulant practice with well monitored quality assurance is likely to be of benefit to both clinicians and the increasing numbers of patients on lifelong anticoagulant therapy. Outcome measures that may be achieved include:

- Better use of consultant time. Reduced routine clinic input, permitting increased input into management of unstable patients and investigation of pre-thrombotic disorders.
- Reduced inpatient stay to achieve stable anticoagulation.
- Reduction in surgery related thromboembolic complications.
- Reduction in near miss events and potential litigation problems.
- More rapid and more local services.

Clinical audit should become an integral component of all anticoagulant services, in conjunction with the very successful laboratory quality assessment schemes.

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