Knowledge Base of Clinicians Regarding Oral Anticoagulant Therapy in a Teaching Institution - A Questionnaire Survey

N Kakkar, R Kaur

Abstract
Aims: Maintaining international normalized ratios (INRs) within the therapeutic range for patients on oral anticoagulant therapy is a tough task. Physician practices have a vital bearing on safe management in these patients. We sought to assess the knowledge base of clinicians in our hospital regarding oral anticoagulant treatment.

Methods: A retrospective review of 3152 consecutive INRs in patients on outpatient oral anticoagulant treatment (OAT) was carried out over a 16 month period. To assess clinician practices, we performed a questionnaire survey (20 questions) on various aspects of OAT among 65 clinicians (response rate - 89%).

Results: 76.3% of the INRs were in the sub-therapeutic range, 19.1% in the therapeutic range while 4.6% INRs were beyond therapeutic range. Fifty five completed questionnaires were returned by 24 consultants and 35 residents. Knowledge of clinicians regarding the loading dose of the oral anticoagulant, target INR range, the colour of the tablet was not adequate with 21, 28 and 23 correct responses respectively. Documentation of dietary and drug history was inadequate with 13 and 38 responses respectively. Patient education was limited to only verbal information to patients on anticoagulation. Most clinicians performed baseline screens before starting therapy. Although majority of clinicians (41) reported haemorrhagic complications in patients, just under one-third (28.8%) clinicians encountered thrombosis more often. Significant differences between the knowledge of consultants and residents was only found in responses for the correct loading dose (p < 0.0007) and the laboratory methodology in use for PT/INR determination (p < 0.04).

Conclusions: Knowledge base of clinicians regarding oral anticoagulant management was unsatisfactory. A tendency to under-dose patients was observed. There is need for stricter adherence to accepted guidelines of anticoagulant therapy with particular emphasis on patient education.

INTRODUCTION
It has been six decades since dicoumarol was first used clinically. Coumarin anticoagulants are well established agents used to counter thrombotic conditions in clinical practice. However, their use has weathered many storms and swings in popularity. Various indications for starting oral anticoagulants have been subjected to much debate over the years. Still none of the thrombotic indications for which they are used represent absolute indications. In each case, the risk of bleeding on treatment has to be weighed against the benefit of preventing thromboembolism for the underlying medical condition.

Managing patients on long term anticoagulants is a complicated task for the clinician. It involves frequent laboratory testing, dosage regulation, prompt diagnosis and treatment of thromboembolic or hemorrhagic complications along with patient education and keeping a track of the compliance factor. Most clinicians are confident that they are well versed in the practical aspects of management, yet the literature suggests that many undesirable effects of therapy result from inappropriate management rather than patient non-compliance or other aberrations.

This study was undertaken to assess the knowledge base of clinicians regarding oral anticoagulant management in our hospital.
hospital. The study was initiated because an alarming number of international normalized ratios (INRs) were not in the optimal range. We report our findings and make recommendations.

**Material And Methods**

This study was conducted in the hematology section of the Department of Pathology, Christian Medical College and Hospital, Ludhiana. The hematology laboratory handles approximately 2500 requests annually for prothrombin time/international normalized ratio (PT/INR) estimation for outpatients on oral anticoagulants. A retrospective review of all PT/INR records over a 16 month period from February 2002 to May, 2003 was carried out. Patients from all services of the hospital who were on oral anticoagulant therapy for various clinical indications were included. The hospital does not run a special anticoagulation clinic and patients are managed by consultants of individual units. In the laboratory, prothrombin time was performed manually using rabbit brain thromboplastin (Tulip diagnostics) with an assigned international sensitivity index (ISI) of 1.2. The therapeutic range considered for most clinical settings was 2.0-3.0 while for patients with prosthetic mechanical valves and those with recurrent deep vein thrombosis, the therapeutic range used was 2.5-3.5. International normalized ratio (INR) values below and above the therapeutic range were deemed sub-therapeutic and over-therapeutic respectively.

To assess clinicians practices related to oral anticoagulant treatment, we designed a questionnaire with 20 questions regarding various aspects of management of patients on such therapy. These were given to clinicians from cardiology, neurology, general medicine, cardio-thoracic and general surgery services all of whom had experience in managing patients on oral anticoagulant therapy. Anonymity was maintained. The clinicians included senior and junior consultants and resident junior doctors who rotated in various units. Questionnaire responses were evaluated collectively for all clinicians as well as separately, comparing the knowledge base of consultants with that of the rotating junior doctors. Fisher’s exact test was used to compare the knowledge base of consultants with that of residents.

The questions pertained to a) patient evaluation and education - the indication for starting oral anticoagulant therapy, drug used, the target INR range defined, documentation of the dietary and drug history, baseline screens for coagulation, liver and renal functions along with information, verbal or in print, given to patients regarding the risks of oral anticoagulants and b) management practices - including the loading dose used by clinicians, their response to high INRs, intervals of INR testing after stoppage of the drug, the dose with which the drug was restarted, the knowledge of color of different strengths of the drug used, and the clinicians’ satisfaction with patient compliance and follow up. Also queried were the practices followed while switching over from intravenous to oral anticoagulants and knowledge of the laboratory method being used to determine PT/INR.

**Results And Analysis**

We analyzed 3152 consecutive PT/INR values over the 16 month study period amongst outpatients on oral anticoagulants. Alarmingly, only about one-fifths of the PT/INR values were within the therapeutic range, the majority being sub-therapeutic with few patients being over-anticoagulated (Fig. 1). We thereafter conducted the questionnaire survey among clinicians in our hospital regarding outpatient oral anticoagulant therapy. Sixty five clinicians in our hospital regarding outpatient oral anticoagulant therapy. Sixty five clinicians returned the questionnaire with a response rate of 89%. Six questionnaires were incomplete and were excluded from the analysis. The questionnaire responses were assessed for 59 clinicians (24 consultants and 35 residents). The results were -

The clinical indications for which oral anticoagulants were used are listed in Table 1.

### Table 1: Shows the indications for which clinicians used oral anticoagulants in their patients

<table>
<thead>
<tr>
<th>Clinical Indication</th>
<th>Number of Clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep vein thrombosis</td>
<td>13</td>
</tr>
<tr>
<td>Post-myocardial infarction</td>
<td>1</td>
</tr>
<tr>
<td>Venous thrombosis- cortical</td>
<td>1</td>
</tr>
<tr>
<td>Portal and mesenteric</td>
<td>1</td>
</tr>
<tr>
<td>Dilated cardiomyopathy with left ventricular clot</td>
<td>1</td>
</tr>
<tr>
<td>Cardio-vascular accident (thrombotic)</td>
<td>1</td>
</tr>
<tr>
<td>Transient ischemic attack</td>
<td>1</td>
</tr>
<tr>
<td>Post percutaneous transluminal angioplasty</td>
<td>1</td>
</tr>
<tr>
<td>Post valve repair</td>
<td>1</td>
</tr>
<tr>
<td>Post valve replacement</td>
<td>1</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>1</td>
</tr>
<tr>
<td>Refractory nephrotic syndrome</td>
<td>1</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>1</td>
</tr>
<tr>
<td>Following arterial graft</td>
<td>1</td>
</tr>
</tbody>
</table>
Baseline screens for coagulation, renal and liver functions were performed before starting anticoagulant therapy according to 54, 52 and 40 clinicians respectively.

Thirty one clinicians responded that they aimed to achieve a target INR of 1.5 to 2.0 while 28 clinicians aimed for a range of 2.0-3.0.

The loading dose of nicoumarol employed by 21 clinicians was 4 mg per day while 30 of them used 2 mg per day to initiate treatment. Eight clinicians used a 1 mg loading dose in their patients.

Thirty one clinicians said that they stopped the anticoagulant drug in response to a high INR value while the remaining continued the drug but with a reduced dose. A repeat PT/INR estimation in such cases was carried out after 48 hours of the deranged INR result by 29 clinicians while 18 and 12 clinicians asked for PT/INR estimation after 24 and 72 hours respectively.

Fifty eight clinicians responded that they reduced the dose of the anticoagulant once it was restarted following stoppage in view of a high INR.

Twenty eight clinicians correctly stated that they would start the oral anticoagulant drug in patients on the same day of starting heparin. There were 41 correct responses on doing a prothrombin time evaluation on the third day of starting the drug.

Fifty four clinicians said that verbal information to patients on oral anticoagulants and the risk of the under or over-anticoagulated state was given while 53 clinicians admitted that no educational information in print was provided prior to initiation of treatment.

Nearly three-fourths of the clinicians opined that the follow up interval in their patients was satisfactory while just over 50% of clinicians were sure of patient compliance.

The fact that the oral anticoagulant drug used was available in the same (white) color even for different strengths was known only to 23 clinicians; 15 clinicians wrongly assumed that the drug was color coded for different strengths while 21 clinicians did now know the color of the anticoagulant drug.

Thirty one clinicians were right in stating that the laboratory was using manual methods for estimation of prothrombin time. Eleven clinicians were wrong in assuming automated estimation while nine clinicians admitted ignorance of the laboratory methodology that was being used.

Forty one clinicians recounted seeing bleeding complications among their patients more commonly while 17 said that they encountered thrombosis progression more often. One response was for not seeing either complication.

Comparison of questionnaire responses between consultants and residents was made by using Fisher’s exact test. Among other questions, we specifically compared the correct responses given by consultants and residents regarding the loading dose of acenocoumarol, the target INR range, knowledge of the color of the tablet, the laboratory methodology in use and the day when oral anticoagulant treatment was initiated in patients who were earlier given intravenous heparin.

Only the knowledge of the loading dose and the laboratory methodology for prothrombin time showed a statistically significant difference between the two groups (Table 2).

Table 2: Shows the correct responses by consultants and residents to questions pertaining to loading dose, method of doing prothrombin time (PT), target INR range, tablet colour and the day of starting oral anticoagulant treatment after initiating therapy with intravenous heparin.

<table>
<thead>
<tr>
<th>Query</th>
<th>Number of correct responses</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loading dose*</td>
<td>15</td>
<td>6</td>
</tr>
<tr>
<td>Lab method*</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Target INR</td>
<td>12</td>
<td>27</td>
</tr>
<tr>
<td>Tablet colour</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>Day of starting OAT</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>
*Only differences for these two questions between consultants and residents were statistically significant.

**DISCUSSION**

Clinical practice has seen a steady increase in anticoagulant use all over the globe. With its narrow therapeutic range for efficacy and adverse events, the trend can lead to greater morbidity and mortality making it an increasingly significant clinical, economic, medico-legal and public health issue.6

Because of the inherent individual fluctuations in response, oral anticoagulant treatment requires frequent monitoring. One of the challenges of such management is the problem of determining the cause of non-therapeutic prothrombin times especially in patients who remain stable for long periods.7

While anticoagulants are clinically indicated to counter thrombotic events, inappropriate dosage and subtherapeutic INR maintenance can result in serious thromboembolic complications. The therapeutic range for INR is narrow and the rate of adverse events, hemorrhagic or thrombosis is related directly to the adequacy of therapeutic control.1 This aspect of oral anticoagulant treatment thus requires special attention. Safe levels of anticoagulation are considered to be achieved if patients are maintained in the therapeutic INR range 70% of the time.8 However there is evidence to suggest that this is not always the case.9,10

Various studies have assessed clinician practices regarding anticoagulant use and their effect on the therapeutic effectiveness or failure of anticoagulation. Yermiah et al implemented an improvement programme including clinician and patient education along with procedural changes covering all aspects of anticoagulant therapy in a study of 110 patients on long term oral anticoagulant therapy for prosthetic valves and atrial fibrillation. They reported an increase of 11% in the proportion of patients whose INR fell within the therapeutic range.11

A study on the dosage practices of clinicians for...
anticoagulation with warfarin during rehabilitation was undertaken by Schaufele et al in 181 patients receiving chronic anticoagulant therapy. Their conclusion was that despite frequent clinician monitoring, there was difficulty in maintaining INRs in the therapeutic range and an overall tendency for underdosing was observed. In our study too, we found a large proportion of INRs to be sub-optimal.

Schlichit et al reviewed clinician practices regarding anticoagulation and cardioversion of atrial fibrillation in a 700 bedded teaching hospital. They reported that in 35% of the cases, clinicians digressed from standard guidelines, thus increasing patient’s risk of stroke. Tan et al (1993) reported poor documentation of diet and drug history in their audit of 100 patients on anticoagulants. Fifty eight percent of the INRs in their study were subtherapeutic. They also found less than satisfactory baseline screen data in the patients.

An important observation in our study too was the poor documentation of the drug and dietary history which can have a bearing on fluctuations in the INR. There have been instances in literature where seemingly innocuous alterations in diet have resulted in serious destabilization of anticoagulation in patients on oral anticoagulants. This further emphasizes the need for documenting a meticulous dietary history. Although in our survey, the query on coagulation, renal and liver function screens had sufficiently large responses, we feel that these would be done as routine for most patients and might not be done with the oral anticoagulant therapy in mind. Some clinicians used inadequate loading doses of dicoumarol and alarmingly, 53% of clinicians aimed for a subtherapeutic target INR range. Sufice to say that their patients would have been underdosed. We must add here that although it is possible that selected patients because of their age or a specific clinical indication could have required lower loading doses or a lower target INR, an overall trend towards underdosing was still observed.

The vital aspect of patient education was also ignored with clinicians limiting themselves to verbal communication (the recall of which is poor) only regarding the risks of anticoagulation while no educational material or a PT booklet was provided to the patients. An important factor in the management of patients on oral anticoagulants is drug dosage. A large number of clinicians were unaware that different strengths of dicoumarol were available in the same color. In patients with poor literacy levels, and with clinicians often prescribing alternating strengths for different days, lack of a color code provides the perfect setting for inappropriate dosing among patients. It is therefore very important that clinicians educate patients regarding various aspects of drug dosage adequately.

On personal interaction with some clinicians following the initial survey, practical problems regarding outpatient management of patients on oral anticoagulants were discovered. In a center where a significantly large clientele has a rural background and whose literacy levels are low, with no specialized health care facilities available in the villages or small towns, clinicians admitted to being wary of the risk of bleeding.

A natural fallout hence was the tendency to under-anticoagulate than being too enthusiastic in stretching dosages to pursue the target INR. Although clinicians recounted seeing more episodes of bleeding than thrombosis in their patients, the fact that 28.8% of the clinicians encountered thrombosis is quite disturbing as this was the primary event for which anticoagulants were given in the first instance and hence signifies failure of treatment.

The overall knowledge base of consultants and residents was statistically comparable. However for two questions statistically significant differences were found between the two groups with consultants having better information of the loading dose while more residents knew the laboratory method in use for determination of PT. The latter is easily explainable as the residents keep on visiting the laboratory often for various tests results and hence would be more aware of the method in use.

The important finding of this study is a wary approach to anticoagulant treatment by clinicians. Greater collaboration between clinicians and the laboratory seems necessary together with strict quality assurance procedures with respect to INR testing. Careful pre-therapeutic assessment of patients, attention to patient education and strict documentation can make anticoagulation a safer bet for patients taking these drugs. The success of special anticoagulation clinics worldwide has shown how this vital area of anticoagulation treatment can be made safer for patients. The enormous cost that these facilities incur can however be a restricting factor in developing countries.

CONCLUSIONS

The knowledge base of clinicians regarding oral anticoagulation was unsatisfactory. A tendency to under-anticoagulate patients was observed which also explains the large number of sub-therapeutic INRs that we have found in the laboratory records. There is need for stricter adherence to guidelines along with greater emphasis on patient education.

Acknowledgements

The authors thank Dr AS Bhatia for assistance in the statistical analysis; Mr. Daniel and other technical staff of the hematology laboratory for diligently maintaining the coagulation records which we could access for our study. We gratefully acknowledge the co-operation of all clinicians who participated in the survey.

REFERENCES


---

**Announcement**

The Association of Physicians of India

**Orations**

Suggestions are invited from members of the Association of Physicians of India for the following assignments so as to reach Dr. Sandhya Kamath, Hon. General Secretary, not later than **20th December, 2004**.

**Dr. GS Sainani Oration - 2006**

**Ranbaxy Oration - 2006**

**Hoechst Senior Lectureship - 2006**

The nomination/application forms for the above orations - kindly see the October 2004 issue, page 846 of *JAPI*.

The recommendations for the above assignments must be accompanied with reasons for recommending a particular person showing the value of his/her research and 8 copies each of three of his/her publications. All papers in connection with the suggestions such as the bio-data, list of publications etc., should be submitted in 8 sets by the proposer, the recipient of the above oration should deliver a lecture pertaining to his/her work at the Annual Conference of API in January, 2006.

The completed application form for the above assignment should reach to Dr. Sandhya Kamath, Hon. General Secretary of API, Unit No. 6 and 7, Turf Estate, Off. Dr. E Moses Road, Opp. Shakti Mill Compound, Near Mahalaxmi Station West, Mumbai - 400 011.

Those who have already been confirmed an Oration/Lectureship/Award are not eligible.

The members of the Governing Body of API and the members of the Faculty Council of ICP are not eligible to receive any Oration/Lectureship/Award.

Dr. Sandhya Kamath
Hon. General Secretary