Quality Assurance Evaluation Study of an Anticoagulation Clinic in Saudi Arabia

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Abstract

A quality assurance project was conducted at King Faisal Specialist Hospital and Research Center to assess the appropriateness of monitoring of patients under the care of the Anticoagulation Clinic.

The findings from reviewing 148 cases identified several areas which deviated from the anticoagulation monitoring protocol. However, the incidence of thromboembolic and bleeding complications in the studied patient population compared favourably with published data. Drugs such as aspirin and co-trimoxazole which may cause potentially serious interactions with warfarin were prescribed in a small but significant percentage of patients taking warfarin. The patients' compliance rate to their clinic appointments was considered acceptable, considering the inaccessibility of anticoagulation clinics for some patients who live in the rural areas of Saudi Arabia.

Improvement in adherence to internationally recommended anticoagulant monitoring protocols, within the limitations of the unique situation in Saudi Arabia, and in patient education regarding self-monitoring of warfarin side effects, may help to reduce complications due to warfarin therapy and thereby ultimately decrease health care costs. The establishment of more primary health care centres with anticoagulant monitoring facilities may also contribute to this goal.

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Introduction

Warfarin is the main agent used in the anticoagulant therapy of many thromboembolic disorders. Although oral anticoagulant therapy has been used for many years and most indications are well defined, the importance of careful monitoring and patient education to maximise benefits and minimise complications cannot be overemphasised. Haemorrhage remains the major complication of long-term therapy with oral anticoagulants.[1-4] Medical literature cites the incidence of minor and major haemorrhage with long-term therapy as varying from 3.6 to 40% and 5 to 25%, respectively.[1,5-8]

Anticoagulation clinics have been established in many hospitals to provide improved anticoagulant control and a reduction in haemorrhagic and thromboembolic complications.[5,9,10] Garabedian-Ruffalo et al. reported that a warfarin anticoagulation clinic staffed by specially trained pharmacists provided better therapeutic control compared to treatment received by patients before their referral to the clinic.[9] An anticoagulation clinic was established at King Faisal Specialist Hospital and Research Center (KFSH&RC) in 1983 to achieve the above-mentioned objectives. The anticoagulation clinic was staffed by physicians, without any pharmacist involvement. No formal monitoring protocol was established prior to the time of this study. In this quality assurance project, we constructed and tested a step-by-step monitoring protocol for warfarin therapy, which was used to audit warfarin therapy in patients at the KFSH&RC Anticoagulation Clinic. The objective of the study was to determine the appropriateness of warfarin therapy by physicians at KFSH&RC prior to the introduction of a monitoring protocol.

Method

This quality assurance project was commenced 2 years after the establishment of the Anticoagulation Clinic. Case histories of patients receiving warfarin during the 18-month period January 1985 to June 1986 were retrospectively evaluated. The audit was conducted by comparing each patient's anticoagulant therapy and frequency of monitoring to an anticoagulant monitoring protocol developed from thorough medical literature review[5,11-15] and approved by the Director of the Anticoagulation Clinic. The explicit evaluation criteria of the warfarin protocol are given in Table 1 with the corresponding references listed. A monitoring form was developed to facilitate collection of data from patient records. The results of the review were coded and subjected to computer analysis.

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Table 1. Monitoring criteria for patients on warfarin therapy

1. Pretreatment prothrombin time (PT) should be performed.[14]
2. If patient is receiving full dose heparin for an acute event, warfarin may be started concurrently or after stabilisation of the heparin dose.[13]
3. Warfarin and heparin therapy should overlap for at least 5 days or until PT is in therapeutic range for two consecutive days.[13]
4. Initial warfarin dosage should be 5–10 mg daily.[11,12]
5. Measure PT daily until stabilised (PT with minimal fluctuation under a constant warfarin dose) for a minimum of 5 days.[13]
6. Maintain PT at 1.5–2.5 times the control.*[5,13]
7. Patients should be seen once a week for three weeks following discharge.[14]
8. Check PT at least every 6 weeks after stabilisation.[5,12]
9. Warfarin should be prescribed for a minimum of 6 weeks or while the precipitating cause exists.[5,12]
10. PT outside the therapeutic range should result in dosage adjustment.[11]
11. PT should be done within one week following any alteration in therapy.[14]
12. Bleeding complications are defined as:
(a) minor bleeding (bleeding episodes not requiring hospitalisation, transfusion or cessation of therapy);
(b) major bleeding (bleeding episodes necessitating hospitalisation, transfusion or discontinuation of therapy).
13. Any reported incident of bruising or bleeding should result in blood analysis and/or stool guaiac determination.[5]
14. Any reported incident of blood in urine should result in a urinalysis.[5]
15. Patients should not miss more than 15% of their clinic appointments.[16]
16. Drugs which have been reported in the litertaure to cause a significant interaction with warfarin should be used with caution.

* International Normalised Ratio was subsequently adopted

Results

A total of 148 cases were available for review. Ninety-one males and 57 females were monitored in the Anticoagulation Clinic for a duration of 259 patient-treatment years. The mean age of the study patients was 30.7 ± 13 years. The majority of patients (68.2%) were prescribed warfarin for mitral valve replacement alone or in conjunction with aortic valve replacement. Other indications for warfarin use are listed in Table 2.

Table 2. Indications for warfarin therapy

Indications	No. of patients	%
Deep venous thrombosis	12	8.1
Pulmonary embolism	5	3.4
Mitral valve replacement	51	34.4
Aortic valve replacement	21	14.2
Mitral and aortic valve replacement	50	33.8
Atrial fibrillation	3	2.0
Transient cerebrovascular accident	6	4.1
Total	148	100.0

Results in our study population were as follows:

1. A pretreatment prothrombin time (PT) was performed in 96.6% of patients.

2. In all patients receiving full dose heparin, warfarin was started either concurrently or after stabilisation of the heparin dose.

3. In all patients the heparin infusion was continued for at least 5 days after initiation of warfarin therapy, or until the patient's PT was in the therapeutic range.

4. All patients received a loading dose of 5–10 mg of warfarin for three consecutive days.

5. In 91.2% of patients, the PT was measured daily until stabilised for a minimum of 5 days.

6. At the time of discharge, 79.7% of patients had a PT which was maintained within the range of 1.5 to 2.5 times the control value.

7. Following discharge from the hospital, 64.6% of patients were seen weekly for three weeks.

8. The PT was checked every six weeks in 82.5% of patients at their clinic visits and every 8–12 weeks in the remaining 17.5% of patients.

9. All patients received warfarin for a minimum of 6 weeks.

10. Dosage adjustments were made in 97.3% of patients whose PTs were outside the therapeutic range.

11. When alterations were made to therapy, 72.6% of patients had their PT measured within the following week.

12. Two per cent of patients (1.16% per patient-treatment year) developed major bleeding complications and 27.5% of patients (15.3% per patient-treatment year) developed minor bleeding complications.

13. Only 10% of patients who developed bruising or bleeding had blood analysis or stool guaiac determinations performed.

14. Only 33.3% of patients who reported blood in their urine had urinalysis performed.

15. Nineteen percent of patients missed more than 15% of their clinic appointments.

16. Warfarin was concurrently prescribed for 12.2% of patients who were on other drugs which may interact with warfarin. Co-trimoxazole (6%) and aspirin (3.4%) were the potentially interactive drugs most commonly prescribed with warfarin.

Discussion

The risk of adverse effects associated with warfarin therapy can be minimised by proper patient education and close monitoring by anticoagulation clinics.[5,9] The present study identified several points which deviated from the generally accepted procedure for monitoring warfarin therapy (Table 1). Although some patients are discharged from hospital with prothrombin times less than 1.5 times the control, it is essential that they be followed up as outpatients each week for the next three weeks for further dosage adjustment. The study indicated that 35.4% of patients were discharged from the hospital without a clinic appointment in the following 3 weeks. This finding may be explained by the unique situation at the KFSH&RC. Almost 50% of all patients who visit the Anticoagulation Clinic live outside Riyadh, within a perimeter of about 1000 kilometres. KFSH &RC is one of the few government hospitals which performs mitral valve replacement surgery. Under the

present Saudi health care system, patients treated in KFSH&RC are preferably followed up by the same institution. As a result, the hospital pays the cost of airline tickets for patients who live a long way from Riyadh (e.g. Eastern Province) to come to KFSH&RC Anticoagulation Clinic for follow-up visits. Because of the difficulty of travelling to Riyadh at frequent intervals and the associated cost, the physicians adjust the frequency of patients' follow-up visits according to where they live. In general, those patients who live in Riyadh are asked to attend at frequent intervals as is usually suggested in the literature. Due to these unusual circumstances, about 17.5% of the patients (all residing outside of Riyadh) were given follow-up appointments every 8–12 weeks.

The literature also recommends that a patient's prothrombin time should be checked within one week following any alteration in therapy and that urinalysis and stool guaiac determination should be performed to investigate any bleeding reported by the patient. It is very difficult for these recommendations to be followed in patients who live outside of Riyadh and this was reflected in our audit results.

It would be expected that, under a less stringent monitoring protocol, the incidence of warfarin-related bleeding would be higher. However, in this study, the percentage of patients who developed bleeding complications was similar to that reported in the literature.[5-7] This may be related to the relatively young age of the patient population in our clinic.

Many drugs which interact with warfarin have been reported in the literature.[8,12] This study revealed that 6% of patients were prescribed co-trimoxazole and 3.4% of patients were prescribed aspirin. Although these patients were subjected to a higher risk of bleeding,[3] none developed serious complications. Physicians and pharmacists should be alerted to avoid combinations of such drugs unless the patient is monitored closely.

Haynes suggested a rate of 15% for missed clinic appointments as acceptable for routine follow-up care in the general population.[16] The rate of missed clinic appointments in this study was 19%, indicating a fairly good compliance rate to clinic appointments, especially with such a large percentage of out-of-town patients. Non-compliance with clinic appointments (19%) in our patient group did not appear to be a substantial problem compared to a rate as high as 50% reported elsewhere in the world.[17] Nevertheless, the clinic non-compliance rate may be higher in rural areas in Saudi Arabia due to the inaccessibility of anticoagulation clinics for these patients.

Conclusions

The overall results indicate good anticoagulant control for patients attending the Anticoagulation Clinic. However, patient follow-up and the monitoring of bleeding episodes reported by the patient could be further improved, although limited by local circumstances. Patients who live outside Riyadh may not be able to travel to Riyadh as frequently as desired but alternative methods of monitoring should be sought to ensure safety of warfarin therapy. Establishing more primary health clinics in Saudi Arabia with anticoagulation monitoring protocols may help to decrease complications of warfarin therapy and ultimately help to decrease health care costs.

References

1. ForFar JCA. A 7-year analysis of haemorrhage in patients on long-term anticoagulant therapy. Br Heart J 1979; 42: 128–32.

2. Davis FB, Estrach MT, Samson-Corvera EB, et al. Management of anticoagulation in outpatients. Arch Intern Med 1977; 137: 197–202.

3. Landefeld CS, Cook EF, Flatley M, et al. Identification and preliminary validation of predictors of major bleeding in hospitalized patients starting anticoagulant therapy. Am J Med 1987; 82: 703–13.

4. Gray DR, Garabedian-Ruffalo SM, Chrelien SD. Cost-justification of a clinical pharmacist-managed anticoagulation clinic. Drug Intell Clin Pharm 1985; 19: 575–80.

5. Errichetti AM, Holden A, Ansell J. Management of oral anticoagulant therapy. Arch Intern Med 1984; 144: 1966–8.

6. Bell WR. Anticoagulant and thrombolytic therapy. In: Harvey AM, Johns RJ, McKusick VA, et al., eds. The principles and practice of medicine. Norwalk: Appleton-Century Crofts, 1984: 515–22.

7. Conte RR, Kehoe WA, Nielson N, et al. Nine-year experience with a pharmacist-managed anticoagulation clinic. Am J Hosp Pharm 1986; 43: 2460–4.

8. Coon WW, Willis PW. Hemorrhagic complications of anticoagulation therapy. Arch Intern Med 1974; 133: 286–92.

9. Garabedian-Ruffalo SM, Gray DR, Sax MJ, et al. Retrospective evaluation of pharmacist-managed warfarin anticoagulation clinic. Am J Hosp Pharm 1985; 42: 304–8.

10. Charney R, Leddomado E, Rose DN, Fuster V. Anticoagulant clinics and the monitoring of anticoagulant therapy. Int J Cardiol 1988; 18: 197–206.

11. Gallus AS. Indications for oral anticoagulant treatment. Drugs 1983; 26: 543–9.

12. Salem HH. Current status of anticoagulants. Drug Therapy 1983; 10: 7–13.

13. Henricks JN. Audit criteria for drug utilization review. Bethesda: American Society of Hospital Pharmacists, 1981: 120–3.

14. Meinhold JM, Reale EO, Miller WA. Audit of anticoagulant therapy of pulmonary embolus, deep vein thrombosis and thrombophlebitis. Am J Hosp Pharm 1979; 36: 214–18.

15. Bradlow BA. Warfarin therapy: a practical guide. S Afr Med J 1983; 64: 317–19.

16. Haynes RB. Strategies to improve compliance with referrals, appointments, and prescribed medical regimens. In: Haynes RB, Taylor DW, Sackett DL, eds. Compliance in health care. Baltimore: Johns Hopkins University Press, 1979: 121–43.

17. Sackett DL, Snow JC. The magnitude of compliance and non-compliance. In: Haynes RB, Taylor DW, Sackett DL, eds. Compliance in health care. Baltimore: Johns Hopkins University Press, 1979: 11–22.