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A retrospective clinical audit of oral anticoagulation management in a general practice surgery

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Background

Oral anticoagulants are predominantly managed in general practice. Warfarin therapy has been the mainstay of treatment although the emergence of newer oral anticoagulants (NOACs) has provided an alternative for some indications[1].
The International Normalised Ratio (INR) is used as a surrogate measure to monitor warfarin safety and efficacy[2, 3]. For the individual patient on warfarin a time in therapeutic range (iTTR) > 60% is considered ideal[4].
For the NOACs e.g. rivaroxaban and dabigatran, routine haematological monitoring is not useful. Recommended management strategies to avoid inadvertent overdose are to:

- dose according to age (dabigatran).
- monitor renal function and adjust dose as per Cockcroft - Gault (C-G) equation [1], using actual body weight (ABW) or ideal body weight (IBW) for overweight and obese patients[1].
- avoid using eGFR (calculated using the MDRD4 equation), as reported by pathology, to guide NOAC management[1],

There also exists other validated factors that increase the bleeding-risk of patients receiving oral anticoagulants[5]. Analyses of the landmark studies of NOACs in atrial fibrillation have concluded that for cohorts of patients with well controlled warfarin management (cTTR ≥ 66%), the benefits of a NOAC in terms of outcomes over warfarin are lost[7].

Aims and Objectives

The primary objective of the audit was to assess the quality and safety of oral anticoagulation in a general practice setting. Outcomes included investigations of:

- iTTR for warfarinised patients; the TTR of the practice warfarin cohort (cTTR) using the Rosendaal method[6];
- renal function monitoring for NOAC patients;
- bleeding risk using the HAS-BLED tool in all patients for the most common modifiable bleeding risk factors.;
- concomitant prescription and over-the-counter medications with the potential to interact with warfarin and/or NOACs

Methods

A 2-year retrospective clinical audit was conducted on records of orally anticoagulated patients who attended a suburban general practice. Data collected and parameters calculated were:

- for warfarinised patients: INRs and target INR range; TTR for individuals (iTTR) and for the cohort (cTTR);
- serum creatinine and eGFR for patients taking NOACs. Creatinine clearance (CrCl) using C-G equation and both ABW and IBW; reported eGFR (using MDRD4);
- bleeding risk factors in all patients using the HAS-BLED^ tool;
- prescribed medications of all patients as recorded in GP software.

Actual anticoagulant-related events were not recorded.

^HASBLED is validated for patients on warfarin for AF, but it was used here to record bleeding risk factors for all patients, although it is recognised that labile INR is not relevant to the NOAC cohort.

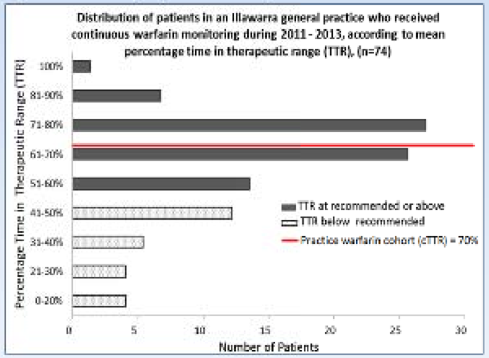
Results

Eighty patients received anticoagulants with a mean age of 75.5 years

Warfarinised cohort - 74 patients (see figure 1)

- The cohort mean cTTR was 70%
- 56 patients (75%) had mean iTTR ≥ 60%, considered ideal[4]
- 19 patients (26%) had a mean iTTR of < 60%, considered less than ideal[4]

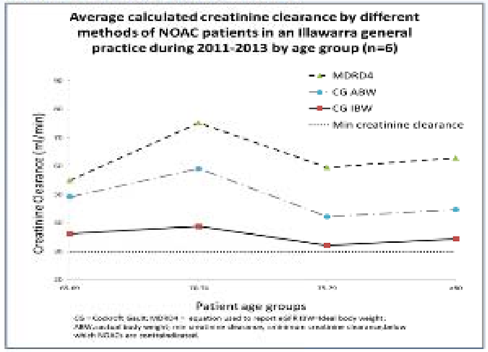
Figure 1 Mean TTR for patients on warfarin


Distribution of patients in an Illawarra general practice who received continuous warfarin monitoring during 2011 - 2013, according to mean percentage time in therapeutic range (TTR), (n=74)
Percentage Time in Therapeutic Range (TTR)
100%
81-90%
71-80%
61-70%
51-60%
41-50%
31-40%
21-30%
0-20%
TTR at recommended or above
TTR below recommended
Practice warfarin cohort (cTTR) = 70%
0
5
10
15
20
25
30
Number of Patients

NOAC Cohort:

- The mean CrCl using C-G equation and IBW was 36 ml/min.
- CrCl using C-G and IBW was lower than both C-G using ABW and the eGFR (calculated using MDRD4 and reported by pathology lab) (Fig 2)
- Three of six patients underwent routine renal function monitoring and dosage adjustment (Table 1).

Figure 2 Creatinine Clearance for NOAC cohort



Results (continued)

All patients - bleeding risk factors (figure 3)

- 44 patients (55%) had ≥ one bleeding risk factor.
- Mean number of risk factors =2, which corresponds to a bleeding risk of 4.1% per annum; or 1.88 bleeds per 100 patient-years[5].
- All NOAC patients had abnormal renal function

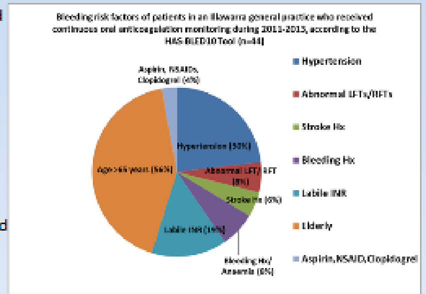

Bleeding risk factors of patients in an Illawarra general practice who received continuous oral anticoagulation monitoring during 2011-2013, according to the HAS-BLED Tool (n=44)
Hypertension
Abnormal LFTs/RFTs
Stroke Hx
Bleeding Hx
Labile INR
Elderly
Aspirin, NSAID, Clopidogrel

Figure 3 HASBLED bleeding risk factors

Table 2 Interacting medications

Medication	No. of patients
Allopurinol	3
Duloxetine	2
Escitalopram	2
Fluconazole	1
Paracetamol	34
Prednisolone	9
Aspirin	1
Clopidogrel	2

Table 1 Renal function and NOAC dose (n=6)

Pt	Age	Mean Creatinine Clearance* CG (ml/min)	NOAC Dose	No. of renal function tests in study period	NOAC dose appropriate #
1	82	42	(D) 110mg BD	3	Yes
2	66	45	(D) 150mg BD	4	No
3	80	33	(D) 110mg BD	1	Yes ²
4	71	43	(D) 110mg BD	2	Yes
5	80	39	(R) 20mg daily	4	No
6	74	34	(D) 110mg BD	2	Yes

CG, Cockcroft-Gault; D, Dabigatran; R, Rivaroxaban; BD, Twice per day. * Mean creatinine clearance calculated using Cockcroft-Gault equation and Ideal Body Weight; #For renal function & age; ² [illegible]

Interacting Medications

59 patients on warfarin (80%) were prescribed interacting medications (Table 2); actual adverse events relating to interacting medications were not recorded. No patients on NOACs were recorded as taking interacting medications.

Conclusion

This retrospective audit of anticoagulation management in the general practice has shown that warfarin management approximates that considered ideal, with the majority of patients achieving an iTTR of high quality control and at a level at which the benefits of the NOACs over warfarin in terms of outcomes are absent[4, 7]. Although there were few patients on NOACS, the results suggest improvement in management is possible. Patients with reduced renal function require more frequent monitoring and where relevant, dose adjustment of their NOACs. A limitation of this audit is that actual bleeding and thrombotic outcomes have not been recorded. Practice wide protocols on anticoagulant monitoring and management should be implemented to improve patient safety.

Acknowledgements:
The GPs, practice nurses and administration staff of Woonona Medical Practice

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