Amiodarone monitoring: involving patients in risk management

Despite amiodarone being a potentially dangerous drug, there is currently no patient-mediated intervention for its monitoring in primary care. This led general practitioner Dr Jill Murie to carry out an audit on the monitoring of amiodarone in her Lanarkshire practice of 13,000. She found monitoring to be suboptimal with some patients being uninformed and at risk.

Abstract

Amiodarone is a potentially hazardous drug indicated for atrial and ventricular arrhythmias. The purpose of the audit was to assess the risk associated with amiodarone therapy and identify measures to improve patient safety. The setting was a rural practice with 13,000 patients in Lanark, Scotland. A computer search identified 16 patients (11 male, five female) receiving amiodarone. The mean age was 74 years (range 61–89 years).

Action taken was raising doctor awareness and systematic biochemical and clinical review. Results showed that, in spite of substantial mortality and morbidity prior to the audit, there was no effective practice monitoring system for amiodarone therapy. The prevalence of clinical hypothyroidism and hyperthyroidism (29%) and 'silent' biochemical thyroid dysfunction (14%) exceeded published estimates (14–18% and 10% respectively). Although standards improved for biochemical monitoring, increasing awareness of the need for close surveillance did not appear to change the practice of some of the general practitioners (GPs), notably the clinical examination of pulse and blood pressure.

The audit demonstrates a need for a more systematic approach to amiodarone monitoring. Recommendations include enhancements to the patient information leaflet, the development of local protocols and patient involvement in quality improvements including improved communication, patient-held record cards, better quality follow-up information, and more effective reporting systems.

Key words: amiodarone, adverse effects, medical audit, patient participation, risk management.

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'Improving patient safety and restoring public confidence in the NHS requires GPs to involve patients in adverse incident reporting'

Jill Murie

Introduction

Potentially dangerous, amiodarone is reserved for when other drugs are ineffective or contra-indicated for atrial and ventricular arrhythmias. Serious side effects are common (table 1) as are drug interactions, which may occur several weeks or months after amiodarone has been discontinued.[1]

Improving patient safety and restoring public confidence in the NHS requires GPs to involve patients and their representatives in adverse incident reporting.[2] This includes events arising from hazardous drug prescribing. There is currently no patient-mediated intervention for monitoring amiodarone in primary care. This audit aims to assess the risk of amiodarone therapy in a large practice and explores systems for risk reduction involving patients and their carers.

The setting for the audit is the rural market town of Lanark with 13,000 people served by nine GPs in purpose built premises with open access to surgeries, treatment room, diabetic clinic and practice patient participation groups.

Criteria and standards

Criteria were derived from evidence-based guidance in the British National Formulary (BNF)[1] and 'best practice' based on clinical experience. Standards took account of problems associated with hospitalisation, doctors' absence and consultations for unrelated complaints (table 2).

First data collection

The first data collection was made on 23rd April 2002. A computer search (GPASS version 5) identified 16 patients (11 male, five female) who had received a script for amiodarone over the previous 41 days. The mean age was 74 years (range 61–89 years). All patients had been seen by a GP in the previous three months.

Table 1. Adverse effects of treatment with amiodarone

Common	Unusual
Photosensitivity (50%)	Pulmonary fibrosis
Rashes	Hypothyroidism and hyperthyroidism
Corneal microdeposits	Peripheral neuropathy
Headaches	Slate-grey skin or melanosis
Tremor	Hepatotoxicity, jaundice and cirrhosis
Disturbed sleep, insomnia, nightmares	Nephrotoxicity and thrombocytopaenia
Vertigo	Hypersensitivity including vasculitis
Gastrointestinal symptoms, nausea	Haemolytic or aplastic anaemia

Table 2. Criteria and standards in the amiodarone audit

All patients on amiodarone are to have:	
• date and place of initiation of treatment recorded	100%
• thyroid function recorded within previous six months	90%
• liver function recorded within previous sx months	90%
• pulse (rate and rhythm) recorded within previous three months	90%
• blood pressure recorded within previous three months	90%
• presence or absence of adverse effects recorded on last visit	70%

The following was found:

- The recording of the date and place of initiation of amiodarone was identified in 94% of cases.
- Four (25%) patient's medical records contained results of thyroid function tests (TFTs) in the preceding six months.
- The same four (25%) demonstrated that liver function tests (LFTs) had been performed in the previous six months.
- Three (19%) patient's records documented a pulse rate but none described a rhythm.
- Six (38%) records contained a blood pressure in the previous three months.
- Four patients (25%) complained of symptoms suggestive of adverse effects specifically cough, (2) dizziness (1) and photosensitivity with gastrointestinal problems and weight loss (1). The other 12 patients' records did not indicate that adverse effects had been actively sought.

Action taken

The audit was presented at a practice meeting and individual cases discussed with the appropriate GP. Where no specific GP was in attendance, the patient was allocated to one doctor for follow-up.

Data collection two

The second data collection was made two months later on 24th June 2002. Two patients had died from cardiovascular causes in the eight-week period (one male, one female) and their records were incomplete. There were no new patients. Of the 14 remaining patients (10 male, four female) the mean age was 73 years (range 61 to 89). All had been seen by GPs in the eight-week period.

The following improvements had been made:

- All patients' records (100%) now recorded date and place of initiation of therapy. The exception previously noted had been in hospital and no discharge information had been received.
- TFTs had been performed on 13 (93%) patients within the previous six months. Six (43%) patients had hypothyroidism (3), hyperthyroidism (1) or biochemical thyroid dysfunction without clinical features (raised TSH [1], borderline raised T4 [1]). The prevalence of overt hypothyroidism and hyperthyroidism was therefore 29%.
- Thirteen (93%) patients' records confirmed that LFTs had been performed in the previous six months. Three (23%) were abnormal.
- Six (43%) patients' records had a pulse recorded in the previous three months. The rhythm was recorded in only three cases.
- Seven (50%) patients' records had a blood pressure recorded in the previous three months. Two were raised – a diabetic (160/90 mmHg) and a patient with a pacemaker (210/90 mmHg).
- There were no additional reports of adverse effects.

Results

Excluding the systematic enquiry for adverse effects, all criteria improved towards the standards we had set, particularly biochemical monitoring, which was usually undertaken by treatment room nurses. Clinical examination of the pulse and blood pressure did not achieve the standards (table 3).

Discussion

In spite of substantial mortality and morbidity, there was no effective practice monitoring system for amiodarone therapy. The sample was high risk – elderly patients with co-morbidity such as diabetes and concomitant medication with which there are interactions.

Increasing awareness of the need for close surveillance did not change some GPs' practice. There was an assumption that if a patient was attending the diabetic clinic or hospital out-patient department, the responsibility for monitoring could be transferred to the specialist.

The prevalence of clinical hypothyroidism and hyperthyroidism (29%) and 'silent' biochemical thyroid dysfunction (14%) exceeded published estimates (14–18%[3] and 10%[4]

Table 3. Audit summary

Aim: to improve patient care and reduce harm				
	23.04.02	**23.06.02**	**Change**	**Standard**
Patients on amiodarone	**N=16**	**N=14**		
• date and place of initiation of treatment	94%	100%	+6%	100%
• TFTs recorded within previous months	25%	93%	+68%	90%
• LFTs recorded within previous months	25%	93%	+68%	90%
• pulse recorded within previous three months	19%	43%	+24%	90%
• blood pressure recorded within previous months	38%	50%	+12%	90%
• adverse effects sought on last visit	25%	25%	no change	70%

Key messages

- Amiodarone is commonly associated with potentially serious adverse effects
- Audit can identify inadequate practice systems for amiodarone monitoring
- Patients can contribute to risk management by adverse incident reporting
- Patient-mediated interventions include revelant information, improved communication, shared record cards and effective reporting systems

respectively), but the sample was small and one patient was hypothyroid before treatment. Although two patients were under-replaced, there was reluctance to increase the dose of thyroxine for fear of provoking a cardiac event.

Increased LFTs (23%) were also more prevalent than reported (10–20%)[5] but were considered unhelpful in the presence of cardiac failure and may have been related to alcohol misuse. Reports of cough raised the suspicion of pulmonary toxicity.[6]

Amiodarone levels were not measured nor doses adjusted by GPs. However, dose reduction must be reconciled with loss of therapeutic effect for what is often a potentially lethal arrhythmia.

The patient information leaflet (PIL) dispensed with amiodarone is more legally motivated than patient-orientated. The font size of the text is small (less than 8 pt), its terminology is medical and it makes no reference to the necessity for six-monthly monitoring other than to suggest to the patient that "your doctor may want to arrange tests".

In addition to the development of local protocols to enable prescribers to audit their own compliance with guidance, there are a variety of ways in which to involve patients in improving safety and quality of care:

- Improved communication between prescribers and patients
- Involvement of community pharmacists in the provision of advice and support
- Clearer information on PILs with risk rates
- Patient-held record cards
- Mechanisms for patients to report directly to the Committee on Safety of Medicines (CSM)
- Better quality follow-up information based on patients' experiences
- All suspected reactions reported to the CSM
- Improved links between patients, health professionals, the CSM and the pharmaceutical industry.

'In spite of substantial mortality and morbidity, there was no effective practice monitoring system for amiodarone therapy'

Conclusion

This audit has identified a role for user and carer involvement in patient safety. To this end, the practice patient participation group will design and develop a patient-centred tool to facilitate clinical evaluation and biochemical monitoring.

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