Developing an evaluated patient-mediated intervention for monitoring amiodarone therapy

This short report discusses how patients can be involved in monitoring amiodarone therapy.

Introduction

Amiodarone is used to prevent atrial and ventricular arrhythmias in high-risk patients, such as after a myocardial infarction (MI) and in congestive cardiac failure. Its use has increased since the mid-1990s and, in 2001, around one million prescriptions were dispensed in primary care in England.[1]

Amiodarone therapy should be initiated by a specialist after baseline investigations (chest X-ray, liver and thyroid function tests) are completed. Thereafter, patients should be monitored six-monthly for clinical and biochemical evidence of toxicity by their GP.[2] Adverse effects and drug interactions are common. One meta-analysis involving 2,193 patients assessed the risk of clinically significant adverse effects compared with placebo (table 1)[3] and another with 6,500 patients assessed the absolute reduction in overall mortality (1.4% per year).[4]

Communication of the risk of adverse effects to patients is essential for informed and shared decision-making.[5] However, there is currently no evaluated, patient-mediated intervention for monitoring amiodarone therapy.

The manufacturers of the only proprietary amiodarone (Cordarone X®) provide a patient information leaflet (PIL) as a legal requirement but, in common with leaflets in general, there is doubt as to its effectiveness.[6] In response to a practice-based audit of amiodarone therapy in Lanark,[7] the practice patient participation group (PPG) undertook a study in 2002 to develop and evaluate an intervention for amiodarone monitoring.

'A patient-mediated intervention for monitoring amiodarone therapy has the potential to involve patients in the communication of risk'

Jill Murie

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Method

A booklet was designed and developed by the PPG (figure 1), and evaluated as follows:

1. Self-report questionnaire

Informed by the practice audit report, participants recruited from the PPG compared the booklet and the PIL for Cordarone X® using an assessment tool adapted for the purpose.[8]

2. Focus group discussion

The aim of the discussion was described as 'to develop a tool which is appropriate and acceptable to patients on amiodarone'. The discussion was audiotaped and contemporaneous notes were taken. Comments from the questionnaire survey and the focus group discussion were collated.

3. Assessment by the Plain English Campaign (PEC)

Editorial changes to the booklet were made in accordance with recommendations and an application submitted to PEC for its 'Crystal Mark' for clarity.

Results

Six patients (three male, three female) completed a questionnaire. Their mean age was 69 years (range 57–80), five years younger than patients in the practice audit (mean age 74; range 61–89 years).[7]

About amiodarone therapy

Although 'general information about the condition' scored more highly in the booklet than in the PIL, participants were divided as to how much information should be provided. There were those who expressed the view that 'too much information might scare them' particularly in relation to heart failure, and others who found the information 'a bit bland' given the risks.

About monitoring of amiodarone

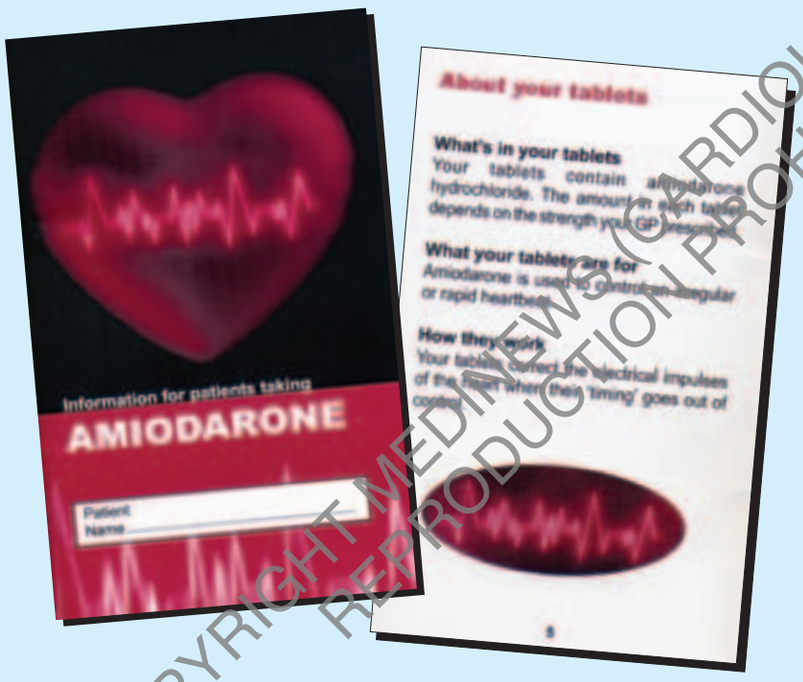
Patients found the 'drug interactions' 'quite complex to take in'. One problem was confusion between the proprietary and generic names of medication. The presentation of the side-effect profile of amiodarone in the PIL provoked an

Table 1. Adverse effects of amiodarone *vs.* placebo

	Odds ratio (95% CI)
Pulmonary (pneumonitis, pulmonary fibrosis)	2.4 (0.9–6.0)
Hepatic (toxicity, jaundice, cirrhosis)	1.2 (0.4–3.5)
Thyroid* (hyperthyroidism, hypothyroidism)	5.1 (2.5–10.3)
Gastrointestinal	1.3 (0.73–2.2)
Neurological* (tremor, vertigo, peripheral neuropathy)	2.1 (1.1–3.9)
Skin* (photosensitivity, slate-grey skin or melanosis)	2.8 (1.2–6.7)
Eye* (corneal microdeposits)	5.6 (2.1–14.8)
Bradycardia*	3.0 (1.9–4.6)

* $p<0.05$ *vs.* placebo

Figure 1. The amiodarone booklet developed by the Lanark practice patient participation group



Box 1
"If it (amiodarone) is as dangerous as it seems I'd just as soon have my 'dickie ticker' because I don't think I could cope with all these side effects."

Box 2
"People that are on the drug are, on average, five years older (than us). Now the booklet is very easy to read. It's got very plain print, whereas in this one (PIL), there is too much room taken up with what I assume is legally required and (there is) not enough room for decent-sized print for patient information.

This thing (PIL) is printed on thin paper, folded up, folded around a bottle and shoved in the carton and will either be ignored or read and thrown away, If someone tries to keep it, it will get lost. It is dreadful and confusing"

emotional response from one patient (box 1).

Information to be recorded on discharge from hospital was welcomed. In relation to thyroid and liver function tests, common themes were the need to know what was 'normal', the clinical relevance of the tests and the avoidance of abbreviations such as T_4, T_3 and TSH.

Presentation

Positive comments about the 'comprehensibility and readability' of the PPG booklet were 'it is clear and jargon-free' with a more appropriate font size print (14) than the PIL (box 2). Additionally, the 'style and tone' of the PPG booklet were described as direct and authoritative without being intimidating.

Application

The potential for shared decision-making was perceived to exist. 'If the patient can understand the significance of the various tests, it will increase their involvement,' was one comment.

Participants discussed the limitation of written information alone in empowering patients. Enablement required support. 'Unless the content of the booklet is explained, page by page, on a one-to-one basis the patient may not realise their personal role in their treatment,' said one patient.

The PPG booklet was considered acceptable in and applicable to either general practice or a hospital setting. It enabled patients to ask 'any relevant questions about the drug' or to disclose 'any new symptom or side effect'. It also facilitated understanding so that 'you could be clear what the doctor is telling you'.

Discussion

An evaluated patient-mediated intervention for monitoring amiodarone has been developed. Evaluation involved triangulating the results of a questionnaire survey and focus group discussion with a formal editorial process by PEC.

The booklet has been endorsed

with the 'Crystal Mark' (9201) for clarity. This is of reassurance to patients. The 'Crystal Mark' also defends clinicians against any accusation that information provided was confusing or liable to be misunderstood, provided that age, reading ability and visual acuity are taken into account.

Obvious weaknesses in the study are the small size of the patient sample who, arguably, might have been biased and the exclusion of patients on amiodarone therapy, who were considered too vulnerable to be exposed to discussion about risk and uncertainty. Generalisation to the patient population on amiodarone with different perceptions and preferences, across time and contexts, is an important issue.

Results of a preliminary evaluation of the PPG booklet by pharmacists in St. Thomas's Hospital, London are encouraging. There is the potential to develop shared-care guidelines for amiodarone monitoring which involve pharmacists, specialists and GPs making explicit their respective responsibilities for monitoring and managing unwanted effects.

The study strengthens the argument in favour of the direct reporting of adverse drug reactions by patients. It also emphasises a need for more pressure to be brought to bear on drug companies to improve their PILs.

Conclusion

A patient-mediated intervention for monitoring amiodarone therapy has the potential to involve patients in the communication of risk. A pilot study will help to determine the intervention's validity and reliability in affected patients and its applicability to different health care settings.

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Conflict of interest

Sanofi-Synthélabo paid for the printing of the booklet but otherwise had no input into the study.

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Jill Murie
Associate Adviser (Clinical Governance/CPD)
Lanarkshire Primary Care NHS Trust/ NHS Education for Scotland, 3rd Floor, 2 Central Quay, 89 Hyde Park Street, Glasgow, G3 8BW.
Correspondence to: Dr J Murie, Woodstock Medical Centre, Woodstock Road, Lanark, ML11 7DH. (email: jillmurie@aol.com)

BOOK REVIEW

Lipids and atherosclerosis annual 2003

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Lipid management is a cornerstone of treatment in the management of cardiovascular disease and has huge implications for primary and secondary care. The editors note that this has produced a rapidly evolving field of research and clinical practice that has only been partly covered in this well-presented book. They have had to pick specific topics covering some basic science and also interesting and frequently encountered clinical management issues.

The book begins with chapters covering the (currently topical) effect of inflammation and that of blood flow (rheological) properties on cardiovascular disease and the non-lipid-lowering effects of medical treatment. These theoretical/experimental chapters are followed by a detailed section outlining the development and mechanisms of action of peroxisome proliferator-activated receptor agonists and fibrates on lipid metabolism in diabetic patients.

There are chapters of practical, clinical interest covering what is (and is not) known about the use of statins in acute coronary syndromes (drawing from the experimental data in the earlier chapters) and their specific effects on high-density lipoprotein cholesterol in primary prevention. Given the exponential increase in their use and the availability of an over-the-counter statin, there is a timely and well-written chapter on the long-term safety of all lipid-lowering drugs and important drug interactions. This is complemented by chapters looking at long-term concordance with lipid-lowering drugs and also at the effect of diet/specific "functional" foods on lipids and cardiovascular disease. Further topics covered are the screening and management of familial hypercholesterolaemia and a comprehensive chapter on lipid management guidelines (with British and European Societies primary prevention charts included).

This is a well-written, concise (approximately 200 pages), almost pocket-sized book that would benefit anyone with an interest in the acute and chronic management of metabolic cardiovascular disease, and the supporting experimental data.

Matthew Dawes
Clinical Fellow and
Consultant in Cardiovascular Pharmacology
Portsmouth Hospitals NHS Trust, PO3 6AD.