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Medicinal mishap

'Statins' and muscle symptoms

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Case

Mr B is 78 years old and has taken simvastatin since 1990. In 1995 he started amiodarone 200 mg daily, but within four months he developed bilateral pain in biceps and thigh muscles. These symptoms have continued on and off since then. He initially brought these symptoms to the attention of his general practitioner, but was reassured that it was not unusual for people in their 70s to suffer from muscle aches and pains.

In late 2003, Mr B's simvastatin dose was doubled to 40 mg twice daily. His symptoms got worse and he tore a muscle while lifting a telephone book. Mr B called the Adverse Medicine Events line (AME Line) querying the possible association between simvastatin and muscle tears, after seeing a similar case reported in a newspaper article about the service. The AME Line classified Mr B as a possible case of statin-induced myopathy due to both a simvastatin-amiodarone drug interaction and a dosage increase. He was provided with published literature on this possible association and advised to return to his doctor for further investigation.

Follow-up revealed that Mr B had an elevated creatine kinase. His dose of simvastatin was subsequently reduced to 10 mg twice daily and ezetimibe was added to his regimen. The patient described gradual improvement of his symptoms over the following eight weeks.

Comment

Mr B's case shows the importance of having a mechanism for consumers to report possible adverse events. Consumer-derived adverse drug reaction reports complement reports from health professionals¹, and may partly address under-reporting of adverse drug reactions by health professionals.²

The AME Line, operated by pharmacists of Mater Health Services Brisbane, was established in October 2003 as a project of the Australian Council for Safety and Quality in Health Care to examine the contribution of consumers to adverse medicine event reporting (both adverse drug reactions and errors related to medicines). Over 2400 consumer reports have been received by the service, with approximately 50% involving symptoms that were ultimately judged likely to be medicine-related. Approximately 20% of the total met the Adverse Drug Reactions Advisory Committee (ADRAC) criteria for reporting, and almost 10% involved medication errors.

Mr B was one of 174 people who called the AME Line with

concerns about 'statin'-induced symptoms, in response to the newspaper article. These cases were associated with:

- increased age
- recent commencement of a statin
- dose increase of the statin
- drug interactions that elevate the statin level, e.g. co-administration of cytochrome P450 (CYP) 3A4 inhibitors such as amiodarone with a statin metabolised by CYP3A4 such as atorvastatin and simvastatin
- pre-existing condition(s) which contribute to an elevated statin plasma concentration, e.g. decreased renal function, dehydration, liver dysfunction or hypothyroidism.

Detailed analyses of these cases, in conjunction with ADRAC, led to the development of a checklist to assist practitioners to determine possible statin-induced musculoskeletal adverse effects (see box).

Conclusion

The AME Line provides an opportunity for Australian consumers to contribute to post-marketing pharmacovigilance. Muscle symptoms with statins may be more common than health professionals suspect.

References

1. van Grootheest K, de Jong-van den Berg L. Patients' role in reporting adverse drug reactions. *Expert Opin Drug Saf* 2004;3:363-8.
2. van Grootheest K, de Graaf L, de Jong-van den Berg L. Consumer adverse drug reaction reporting. A new step in pharmacovigilance? *Drug Saf* 2003;26:211-7.

**Adverse Medicine Events Line 1300 134 237
(Mon–Fri 9am–6pm EST)**

Checklist for statin-induced muscle symptoms

Does the patient experience:

- muscle aches, tenderness, soreness, weakness or pain, usually present in proximal muscles (e.g. trunk)
- bilateral symptoms
- decreased muscle strength (not just feeling tired)
- difficulty in:
 - getting up from a chair
 - holding arms above the head
 - performing usual tasks (generalised difficulty)

Are any of the following concentrations increased:

- creatine kinase
- erythrocyte sedimentation rate
- C-reactive protein