



Media report of rare rhabdomyolysis cases seems to have triggered reluctance among some New Zealanders to use statins

In October 2005, a news item was aired on TVNZ's *CloseUp* that detailed the side effect of rhabdomyolysis related to the use of simvastatin. Two members of the public were interviewed who had experienced rhabdomyolysis and had suffered permanent injury as a result. Two case fatalities in New Zealand were also discussed.¹ Eleven months later, cardiologists are finding that the public are apprehensive about being prescribed simvastatin because of an unjustified fear of a rare side effect.

The evidence supporting the use of statins in primary and secondary prevention of coronary disease is irrefutable.²⁻⁶ Should 11 people with previous myocardial infarction stop taking their statin, one preventable coronary event within that group will occur within 5 years. If 25 people with a similar history were to stop taking their statin there would be one preventable death within the same period.⁴

The penetration of statin use however remains poor.⁷ This is a problem primarily of access to health services but also touches upon the issue of public health education in primary prevention. The importance of cholesterol management is a subject that is probably well entrenched in the collective public consciousness. However what is perhaps not realised is that practise has changed and pharmacological management has become an accepted early intervention in individuals with vascular risk factors, in conjunction with dietary and lifestyle changes rather than following them.⁸

Rhabdomyolysis associated with the statin drug class is rare. Fatal rhabdomyolysis is considered to be an extremely rare complication of statin use, lower than one case per million prescriptions.⁹ Myositis and myopathy are more common adverse reactions which when recognised early are reversible. Dose reductions, trialling alternative statins, or alternative lipid-lowering agents are all accepted methods of subverting this complication. Testimony to the safety of statins is the fact that the Medicines and Healthcare Regulatory Authority (MHRA) in the United Kingdom has recently approved sale of over-the-counter generic simvastatin.¹⁰ The purpose of such a move was to make the drug more accessible, perhaps to those who cannot afford a doctor's appointment.

Concerningly, Pfizer and Merck have sited zero to negative sales growth in New Zealand for simvastatin and atorvastatin since October 2005.¹¹ With an aging population and reducing targets for LDL cholesterol management, the expectation would be an overall increase in total prescriptions.

Negative publicity has had a significant impact on the perception and uptake of an extremely effective life-saving medication. On a population basis, such an impact could have profound flow on effects. Doctors need to be aware of the potential rare side effects of statins and provide information to patients when prescribing, particularly as many drugs in New Zealand come without product inserts. However prescribers also need to reassure patients that serious adverse reactions are rare and that the potential benefits of remaining on treatment are profound.

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References:

1. Gladding P, Pilmore H, Edwards C. Potentially fatal interaction between diltiazem and statins. *Ann Intern Med.* 2004;140:W31.
2. Pignone M, Phillips C, Mulrow C. Use of lipid lowering drugs for primary prevention of coronary heart disease: meta-analysis of randomised trials. *BMJ.* 2000;321:983–6.
3. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). *Lancet.* 1994;344:1383–9.
4. Shepherd J, Cobbe SM, Ford I, et al. Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. West of Scotland Coronary Prevention Study Group. *N Engl J Med.* 1995;333:1301–7.
5. Downs JR, Clearfield M, Weis S, et al. Primary prevention of acute coronary events with lovastatin in men and women with average cholesterol levels: results of AFCAPS/TexCAPS. Air Force/Texas Coronary Atherosclerosis Prevention Study. *JAMA.* 1998;279:1615–22.
6. Sever PS, Dahlof B, Poulter NR, et al. Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial—Lipid Lowering Arm (ASCOT-LLA): a multicentre randomised controlled trial. *Lancet.* 2003;361:1149–58.
7. El-Jack S, Kerr A. Secondary prevention in coronary artery disease patients in South Auckland: moving targets and the current treatment gap. *N Z Med J.* 2003;116(1185). URL: <http://www.nzma.org.nz/journal/116-1185/664/>
8. New Zealand Guidelines Group. Assessment and Management of Cardiovascular Risk. Wellington: NZGG; 2003. Available online. URL: http://www.nzgg.org.nz/guidelines/dsp_guideline_popup.cfm?&guidelineID=35 Accessed September 2006.
9. Staffa JA, Chang J, Green L. Cerivastatin and reports of fatal rhabdomyolysis. *N Engl J Med.* 2002;346:539-40.
10. Nash DB, Nash SA. Reclassification of simvastatin to over-the-counter status in the United Kingdom: a primary prevention strategy. *Am J Cardiol.* 2004;94(9A):35F–39F.
11. Francis Bengel, Pfizer representative; Brent Hilton. Merck representative; Personal Communication; 2006.