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Title **A Systematic Review and Economic Evaluation of Statins for the Prevention of Coronary Events**

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Aim

To evaluate the use of a group of statins, atorvastatin, fluvastatin, pravastatin, rosuvastatin, and simvastatin, in preventing cardiovascular events.

Conclusions and results

Thirty-one randomized studies compared a statin with placebo or with another statin, and reported clinical outcomes. Meta-analysis of data from placebo-controlled studies indicates that in patients with, or at risk of, cardiovascular disease (CVD), statin therapy is associated with reduced relative risk of all-cause mortality, cardiovascular mortality, coronary heart disease (CHD) mortality, and fatal myocardial infarction (MI), but not of fatal stroke. It is also associated with reduced relative risk of morbidity and coronary revascularization. On the evidence available from placebo-controlled trials, it is hardly possible to differentiate between the clinical efficacy of atorvastatin, fluvastatin, pravastatin, and simvastatin. Some evidence from direct comparisons between statins suggests that atorvastatin may be more effective than pravastatin in symptomatic CHD, but evidence on effectiveness in different subgroups is limited. Statins are considered to be well tolerated and have a good safety profile. Increases in creatine kinase and myopathy have been reported, but rhabdomyolysis and hepatotoxicity are rare. Some patients may receive lipid-lowering therapy for up to 50 years, but long-term safety is unknown. In secondary prevention of CHD, the incremental cost-effectiveness ratios (ICERs) increase with age, between GBP 10 000 and GBP 17 000 per QALY for ages 45 and 85 respectively. Sensitivity analyses show these results are robust. ICERs vary substantially by age and risk in primary prevention of CHD. The average ICERs weighted by risk range from GBP 20 000 to GBP 27 500 for men and from GBP 21 000 to GBP 57 000 for women. The results are sensitive to the cost of statins, discount rates, and the modeling timeframe. In the CVD analyses, the average ICER weighted by risk level remains below GBP 20 000 at CHD risk levels down to 0.5%. A key limitation of the analyses is the need to extrapolate well beyond the timeframe of the trials.

Recommendations

The evidence suggests that statin therapy is associated with a statistically significant reduction in the risk of primary and secondary cardiovascular events. The generalizability of these results is limited, and the treatment effect may be reduced in an unselected population. Modeling shows that statin therapy in secondary prevention is likely to be cost effective. In primary prevention, the cost-effectiveness ratios depend on the level of CHD risk and age, but results from CVD analyses support the more aggressive treatment recommendation in recent guidelines in UK.

Methods

A review was undertaken to identify and evaluate all literature relating to the clinical and cost effectiveness of the listed statins in the primary and secondary prevention of CHD and CVD in the UK (electronic databases were searched between November 2003 to April 2004). A Markov model was developed to explore the costs and health outcomes associated with a lifetime of statin treatment.

Further research/reviews required

Additional high-quality evidence on quality of life and compliance and continuance for patients on statins is required. Large outcome studies at lower risk thresholds would be useful to determine whether the relative risk reduction figures remain valid at lower risk levels and to determine the extent to which potential disutility due to statins may become an issue as treatment is extended to a vast proportion of the 'well' population. Future service implementation research is important, particularly on effective policies for targeting low-risk populations. Research is needed on the attitudes of low-risk patients and relatively healthy 45-year-olds towards taking lifetime medication, along with research into the optimal methods of explaining risks and benefits of treatment to patients so they can make informed choices.

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