Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Simvastatin (HMG coenzyme A-inhibitor) in patients with cardiovascular disease.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Male and female patients with previous myocardial infarction or stable angina pectoris (age range, 35-70 years)

Setting
Secondary care and hospital. The study was carried out in Denmark, Finland, Iceland, Norway, and Sweden.

Dates to which data relate
The data were collected between 19 May 1988 and 1 August 1994. The price year was 1995.

Source of effectiveness data
Single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were reported (to achieve a 95% power to detect a 30% reduction in total mortality at a significance level of two-sided 0.05, 4,400 patients needed to be followed until the occurrence of 440 deaths). A total of 4,444 patients was included in the study. From these, 2,221 were allocated to the intervention, whereas 2,223 were allocated to the comparator. Thirty-seven percent (37%) of the 7027 patients originally recruited for the study were excluded.

Study design
Randomized controlled trial carried out as a multi-centre (94 centres) study. The median duration of follow up was 5.4 years. The randomisation was stratified by clinical site and previous myocardial infarction.
Analysis of effectiveness

The analysis was based on intention to treat. The primary health outcome used in the analysis was risk of CHD death. The study also reported the risk of major cardiovascular event occurrence during a median follow up period of 5.4 years. The groups were comparable in terms of gender, age, diagnosis, time since first diagnosis of angina or infarction, secondary diagnoses, concomitant medications, blood pressure, cholesterol levels, age of men and women, body mass index and heart rate.

Effectiveness results

With respect to the comparator, the intervention resulted in a 30% mean reduction in the risk of death ($p<0.0003$). The risk of major coronary events was reduced in 34%. The relative risk of major coronary events in the intervention was 0.73 (95% CI: 0.66 to 0.8; $p<0.0001$).

Clinical conclusions

Simvastatin reduces mortality and morbidity in coronary heart disease patients.

Measure of benefits used in the economic analysis

CHD death avoidance was the measure of benefits used in the economic analysis.

Direct costs

Costs were discounted. The study measured the cost of complications (costs of hospitalizations and revascularization procedures) and the operating costs (drug acquisition costs). The boundary adopted was that of the hospital. The cost estimation was based on actual data from the clinical trial in question. The unit costs were obtained from 1995 US prices, based on the diagnostic related group (DRG) cost-per-case data. Costs associated with concomitant medications used in both groups were omitted from the analysis as the authors consider them to be common to both strategies.

Currency

US dollars ($).

Sensitivity analysis

Not performed.

Estimated benefits used in the economic analysis

With respect to the comparator, the intervention resulted in a 30% mean reduction in the risk of death ($p<0.0003$). The risk of major coronary events was reduced in 34%. The relative risk of major coronary events in the intervention was 0.73 (95% CI: 0.66 to 0.8; $p<0.0001$).

Cost results

Using a discount rate of 5%, the incremental costs of the intervention relative to the comparator, turned out to be $528 per patient, or, alternatively, $0.28 per day. With nine laboratory measurements of lipids and transaminases assumed for a 5.4 year period (4 in the first year and once a year for the next 5 years), the total incremental cost per patient would be $778, or $0.41 per day.

Synthesis of costs and benefits

Not combined. However, as simvastatin resulted in favourable effectiveness results and also cost less it was the dominant strategy.
Authors' conclusions
This study showed that treating CHD patients with simvastatin resulted in reduced costs for the major cost components of cardiovascular disease, thus implying a major drug cost reduction for the United States.

CRD COMMENTARY - Selection of comparators
The comparator chosen was placebo.

Validity of estimate of measure of benefit
The estimate of measure of benefit is likely to be valid given the study design employed in the effectiveness analysis, which controlled for compliance, demographic characteristics and prognostic factors, and given the adequacy of the sample size. The data were not used selectively to prove any particular point.

Validity of estimate of costs
The validity of the cost results may be open to question, despite the fact that the costs measured accounted for the majority of costs associated with CHD. This results from the fact that the unit cost data used in the analysis related to a different geographical area (US) than that in which the study was carried out (Scandinavia). The assumptions implicit in the cost extrapolation (similarity between regions in terms of frequency of recurrent CHD events, the proportion of such events leading to hospitalization, and the rate of revascularization procedures) were discussed and potential biases were found, which were not investigated in, for example, a multi-way sensitivity analysis. However, costs associated with concomitant medications, outpatient visits, nursing home stays, and indirect costs, were not included in the analysis. The authors dismissed the importance of these omissions for the conclusions of this study.

Other issues
The authors' conclusions were not clearly justified, given the uncertainties in the data. The authors presented the study as the first resource use analysis from prospectively-collected data from a randomized controlled trial of an effective cholesterol lowering intervention. The generalisability of the study results depends on the adequacy of the assumptions reported above. Nevertheless, no synthesis of costs and benefits was carried out, given that the authors restricted the scope of the study to analysing the resource use implication of simvastatin.

Implications of the study
No clear implications can be derived in terms of desirability of simvastatin for treating patients with CHD, given that no combination of costs and benefits was accomplished by this study.

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MeSH
Adult; Aged; Anticholesteremic Agents /therapeutic use; Cholesterol /blood; Coronary Disease /blood /drug therapy /mortality; Double-Blind Method; Female; Health Care Costs; Humans; Lovastatin /analogs & derivatives /therapeutic use; Male; Middle Aged; Simvastatin

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