Cost effectiveness of intensive lipid-lowering treatment for patients with congestive heart failure and coronary heart disease in the US  
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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.

CRD summary
This study assessed the cost-effectiveness of a high-dose versus a low-dose statin for secondary prevention in patients with both congestive heart failure and coronary heart disease. The authors concluded that intensive high-dose atorvastatin might be cost-effective compared with low-dose atorvastatin, but the results were sensitive to the assumptions on mortality. The methods were valid and should ensure the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study assessed the cost-effectiveness of a high-dose versus a low-dose statin, as secondary prevention, for patients with both congestive heart failure (CHF) and coronary heart disease (CHD).

Interventions
Atorvastatin 80mg per day was compared with atorvastatin 10mg per day. Treatment was assumed to last over the patient’s lifetime.

Location/setting
USA/secondary care.

Methods
Analytical approach:
The analysis was based on a Markov model, with a lifetime horizon. The authors stated that the perspective of the payer was adopted.

Effectiveness data:
The clinical data were from a selection of studies. The bulk of the evidence was from the Treating to New Targets (TNT) trial, a multinational trial that compared atorvastatin 80mg versus 10mg for patients suffering from CHD. A subgroup of 781 patients who had CHF and CHD was considered for this analysis. Supplementary data were from other published trials, life tables, and other published studies. The mortalities were the key inputs of the model and these were not from the TNT trial because the mortalities in this trial were half those seen in other recent CHF statin trials.

Monetary benefit and utility valuations:
Health-related quality of life values were from a published study that used the European Quality of life (EQ-5D) questionnaire, with a sample of the US population.

Measure of benefit:
Life-years (LYs) and quality-adjusted life-years (QALYs) were the summary benefit measures. A 3% annual discount rate was applied.

Cost data:
The economic analysis included the costs of drugs and cardiovascular events (minor and major events as well as revascularisations). The data were from published sources that did not include the TNT trial. Only the costs of
immediate (acute) events were considered. Revascularisation weights for surgical procedures (coronary artery bypass graft and percutaneous transluminal coronary angioplasty) were from a large US commercial medical claims database. All costs were in US dollars ($) and were discounted at an annual rate of 3%. They were in 2006 to 2007 values.

Analysis of uncertainty:
In an alternative scenario, the treatment-specific post-event and non-cardiovascular mortalities were estimated using Kaplan-Meier time-to-event analyses and the TNT trial data. After five years, long-term published rates were used, as in the base case. A probabilistic sensitivity analysis was performed using non-parametric bootstrapping for the TNT trial data and predetermined distributions for the published data. Only the drug costs, acute event mortality, and overall mortality were not varied. Cost-effectiveness acceptability curves were generated. A series of one-way sensitivity analyses was also carried out, using plausible ranges of values, for selected inputs. Variations in the price of atorvastatin after five years were also considered.

Results
In the base case, atorvastatin 80mg was $2,000 more expensive than 10mg. The LYs were 8.85 with 80mg and 8.64 with 10mg. The incremental cost per LY gained with 80mg was $9,600 and per QALY gained it was $13,600. Atorvastatin 80mg was cost-effective in 77% of simulations at a threshold of $50,000 and 80% of simulations at $100,000 per QALY.

When using mortality data from the TNT trial, atorvastatin 80mg had the same or fewer LYs and QALYs compared with 10mg. The costs were $1,800 higher with 80mg, making 10mg dominant (more effective and less expensive). Atorvastatin 80mg was cost-effective in only 44% of simulations at a threshold of $50,000 and 48% of simulations at a threshold of $100,000 per QALY.

These findings were generally sensitive to variations in the hazard ratios for resuscitated cardiac arrest, CHF, and myocardial infarction for patients receiving atorvastatin 80mg, and to variations in the cost of atorvastatin 80mg.

Authors' conclusions
The authors concluded that intensive atorvastatin 80mg treatment might be cost-effective compared with 10mg, but the results were sensitive to the assumptions on mortality.

CRD commentary
Interventions:
The comparators were selected on the basis of the TNT trial, which appropriately considered two intensities of drug dosage for the patient population.

Effectiveness/benefits:
The clinical data were mostly from a multinational head-to-head randomised controlled trial that included a large sample of patients. This should have ensured high internal validity and more information was available elsewhere (Khush, et al. 2007, see ‘Other Publications of Related Interest’ below for bibliographic details). Some assumptions were made for the extrapolation of the short-term data to a patient's lifetime. Different mortalities after cardiovascular events were considered as the trial data appeared to be much lower than those found in other publications. Other estimates were also varied in the sensitivity analysis. In general the clinical analysis was presented extensively and satisfactorily.

Costs:
The categories of costs were appropriate for the perspective of the payer. They were not broken down into individual items, but were presented as totals, which is usual for data on cardiovascular events. The sources were not extensively presented, but most of them appear to have reflected the US reimbursement system. The price year and discounting were clearly reported and the key economic inputs were varied in the sensitivity analysis.

Analysis and results:
The projected costs and benefits were appropriately synthesised, using an incremental approach. The uncertainty was satisfactorily investigated, using valid approaches, and several alternative scenarios were analysed. The results of both
the base case and the sensitivity analyses were clearly presented and discussed, except that the expected QALYs were not reported. The authors acknowledged the potential International heterogeneity in the data from the TNT trial and they tested the impact of using only US data instead of pooled data. The sample in the TNT trial included patients with mild CHF and the results cannot be generalised to more severe patients.

Concluding remarks:
The methods were valid and should ensure the validity of the authors’ conclusions.

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