Costs and health effects of adding functional foods containing phytosterols/-stanols to statin therapy in the prevention of cardiovascular disease


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
The objective of the study was to evaluate the benefits and costs of functional foods enriched with phytosterols and phytostanols in addition to statin therapy. The authors concluded that the use of functional foods enriched with phytosterols and phytostanols was not a cost-effective strategy to reduce cardiovascular disease. Overall quality of the study methodology was adequate. Methodology and results were well reported. Given the scope of the analysis, the authors’ conclusions are appropriate.

Type of economic evaluation
Cost-utility analysis

Study objective
To evaluate the benefits and costs of functional foods enriched with phytosterols and phytostanols (PP) in addition to statin therapy.

Interventions
The authors compared current practice (real-life consumption patterns of PP) with an intervention in which at-risk patients were assumed to start PP use.

At-risk patients were defined in two ways: only statin users; and all patients with a SCORE risk of 5% or more. The same comparison was made in a maximum statin use situation.

Location/setting
Netherlands/community care.

Methods
Analytical approach:
A chronic disease model (RIVM, a previously published Markov model) was used to assess the cost-effectiveness of the two interventions under study. The time horizon was 50 years. The perspective adopted in the economic analysis was not reported explicitly.

Effectiveness data:
The clinical and effectiveness parameters were derived from published studies. Many of the model parameters were derived from the same data sources that were used to inform the RIVM model. The main effectiveness parameter was reduction in total cholesterol through intake of PP. This parameter was derived from the dose-response relation identified from a published meta-analysis by Demonty et al. (see Other Publications of Related Interest).

Monetary benefit and utility valuations:
Life expectancy was adjusted for quality using data derived from the Global and Dutch Burden of Disease studies.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary measure of benefit. As benefits could be incurred over a period of 50 years, future benefits were discounted using an annual rate of 1.5% following Dutch guidelines for pharmacoeconomic research.
Cost data:
The direct costs included in the analysis were those relating to the intervention (which included PP, statin use, visits to doctors and lipid tests) and future healthcare costs from diseases averted by using PP and/or statins and from patients who survived longer as a result. Costs of PP were estimated assuming these were incorporated into a bread spread. Costs for doctor visits, statins, and lipid tests were derived from Dutch sources. Future healthcare costs were derived from age- and gender-specific data from a comprehensive Dutch Cost of Illness study. As costs could be incurred over a period of 50 years, future costs were discounted using an annual rate of 4% as recommended in Dutch guidelines. The price year was 2010. All costs were reported in Euros (€).

Analysis of uncertainty:
The authors reported that a probabilistic sensitivity analysis was used to evaluate the combined effect of uncertainty regarding the effectiveness of PP and the levels of cholesterol in the Dutch population. The authors performed a probabilistic sensitivity analysis using 100 Monte Carlo simulations. A series of one-way sensitivity analyses were performed to evaluate the impact of model assumptions and changes in model parameters.

Results
For the Dutch population aged 35 to 74 years of age, current practice resulted in 132,400,000 QALYs and total costs of €895,800 million. Additional PP use resulted in QALY gains of 2,700 and additional costs of €502 million in patients prescribed with statins and QALY gains of 12,400 and additional costs of €1,111 million in patients with SCORE risks of 5 or more. In a scenario with maximum statin use, additional PP use resulted in 16,300 additional QALYs gained and additional costs of €1,388 million.

Costs and benefits were combined using an incremental cost utility ratio (additional cost per QALY gained). When compared to current practice, additional PP use was associated with an incremental cost-utility ratio of €203.00 when only given to patients on statins and €96,400 when given to all patients with a SCORE risk of 5 or more. In a scenario with maximum statin use, additional PP use was associated with an incremental cost-utility ratio of €92,200.

Results of the probabilistic sensitivity analysis showed that at a cost-effectiveness threshold of €50,000 per QALY gained the probability that additional use of PP was cost-effective was zero.

Authors' conclusions
The authors concluded that the use of functional foods enriched with phytosterols and phytostanols was not a cost-effective strategy to reduce cardiovascular disease.

CRD commentary
Interventions:
The interventions under study were reported clearly.

Effectiveness/benefits:
The clinical and effectiveness estimates were derived from previously published studies. Parameters directly influenced by the interventions under study, effectiveness of PPs at reducing total cholesterol and current cholesterol levels in the Dutch population were derived from a previously published meta-analysis and population-cohort study. Brief details of these studies were reported along with full references for the study. Other model parameters were already embedded in the RIVM model and their continued use seemed appropriate. Given that this study had been used quite extensively in the Netherlands it was likely that all relevant information was included in the model. The sources from which quality of life estimates were derived from were reported adequately.

Costs:
The authors did not explicitly report the perspective used in the economic analysis but it was clear that a healthcare system analysis was included in the analysis with all major relevant cost categories and costs included in the study. The sources from which cost information was derived from were reported adequately. The price year, discount rate used, time horizon and currency details were all reported clearly and adequately.

Analysis and results:
Cost and outcome information were synthesised using a previously published Markov model. Adequate details of the...
model structure were given and included references to other studies that used the model and a graphical depiction. Although a probabilistic sensitivity analysis was undertaken, this analysis appeared to evaluate only the uncertainty in two of the models’ parameters and as a result the impact of overall model uncertainty did not appear to have been evaluated. The authors reported that the main limitation of their study was that the model used estimates from studies undertaken in different countries and there was uncertainty about whether these were generalisable to the Netherlands.

Concluding remarks:
Overall quality of the study methodology was adequate. Methodology and results were well reported. Given the scope of the analysis, the authors’ conclusions are appropriate.

Bibliographic details

PubMedID
21816151

DOI
10.1016/j.ejphar.2011.05.081

Original Paper URL

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Cardiovascular Diseases /diet therapy /drug therapy /economics /prevention & control; Cost-Benefit Analysis; Functional Food /analysis /economics /utilization; Health Care Costs; Humans; Hydroxymethylglutaryl-CoA Reductase Inhibitors /therapeutic use; Phytosterols /pharmacology /therapeutic use

AccessionNumber
22011001925

Date bibliographic record published
13/02/2012

Date abstract record published
08/11/2012