A Mediterranean diet is cost-effective in patients with previous myocardial infarction

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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.

Health technology
The study examined the use of a Mediterranean diet for patients with previous myocardial infarction (MI). The key elements of the Mediterranean diet were more whole-grain bread, more fruit, green vegetables and fish, less red meat, no butter or cream, and oils or spreads restricted to olive oil.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The study population comprised patients aged younger than 70 years who had survived an MI in the previous 6 months.

Setting
The setting was primary care. The economic study was carried out in Australia.

Dates to which data relate
The effectiveness and resource use data were derived from studies published between 1999 and 2006. The price year was 2003.

Source of effectiveness data
The clinical data used to populate the decision model were based on the effectiveness of the interventions (rates of cardiac death, nonfatal MI, all-cause death, and minor and major events with Mediterranean diet or prudent Western diet), from which probabilities of transition across health states were calculated.

Modelling
A Markov model was constructed to evaluate the clinical and economic impact of the two dietary regimens. The cost-effectiveness analysis was modelled over a 4-year period using data from a clinical trial, while the cost-utility analysis was run for a 10-year period with the clinical trial data extrapolated to a longer time horizon. The health states, cycle length and transition probabilities were described. The methods used to extrapolate survival data from the clinical trial (4 years) to a longer time horizon (10 years) were also described. The structure of the model was presented.

Sources searched to identify primary studies
Treatment effectiveness was derived from a clinical trial, the Lyon Diet Heart Study, which enrolled 605 patients in France between 1988 and 1992. The study showed that the Mediterranean diet reduced fatal and nonfatal events in
comparison with a Western diet. The characteristics of the hypothetical cohort of patients who entered the decision model were also taken from this trial. Transition probabilities between health states came from the Lyon Diet Heart Study and other clinical trials.

**Methods used to judge relevance and validity, and for extracting data**

The Lyon Diet Heart Study was identified through a systematic review of the literature. MEDLINE and the Cochrane Database of Systematic Reviews were searched for high-quality studies (randomised controlled trials or meta-analysis) evaluating the effect of the Mediterranean diet in patients with previous MI. Of the three randomised, clinical trials identified, data were retrieved from the Lyon Diet Heart Study. The reasons for choosing this study were not explicitly stated, but it might have been chosen because of its large sample size and long-term follow-up.

**Measure of benefits used in the economic analysis**

The summary benefit measures were the quality-adjusted life-years (QALYs) in the cost-utility analysis and cardiac death or nonfatal MI events in the cost-effectiveness analysis. Life-years were also reported. The utility weights used to adjust survival were derived from three published studies that used the time trade-off method. The benefits were discounted at an annual rate of 5%.

**Direct costs**

The authors did not report the cost/resource boundary of the analysis. The analysis was restricted to the direct costs of the Mediterranean diet (food and visits with cardiologist and dietician) and the direct medical costs associated with the treatment of cardiovascular events (angina, MI, heart failure, stroke). The unit costs and the resource quantities were not presented separately. However, a breakdown of the cost categories was given, and the cost per person for different items (initial and follow-up visits, treatment of minor and major cardiovascular events etc.) was reported. Resource use for the interventions (Mediterranean versus Western diet) was derived from the Lyon Diet Heart Study. The costs of food were estimated from a major Australian retailer. The rates of events came from the literature and were costed using Australian diagnosis-related groups. The costs were incurred over a long time and a discount rate of 5% per annum was used. The price year appears to have been 2003.

**Statistical analysis of costs**

The costs and quantities appear to have been treated deterministically.

**Indirect Costs**

The productivity costs were not considered.

**Currency**

Australian dollars (AUD). The costs were also presented in US dollars ($) and euros (EUR). The currency conversion was performed at rates published in June 2004, but the conversion rates were not explicitly reported.

**Sensitivity analysis**

An extensive univariate sensitivity analysis was performed to address the issue of the robustness of the cost-effectiveness and cost-utility ratios to variations in effect size, cost, utility, time horizon and discount rate. The sources of the alternative data were not reported.

**Estimated benefits used in the economic analysis**

Over a 4-year time horizon, the rate of cardiac death/nonfatal MIs was 4.6% with the Mediterranean diet and 14.5% with the Western diet (difference 9.9%).
Over a 10-year time horizon, the mean life-years per person were 7.29 with the Mediterranean diet and 6.98 with the Western diet (difference 0.31).

Over a 10-year time horizon, the mean QALYs per person were 6.62 with the Mediterranean diet and 6.22 with the Western diet (difference 0.40).

**Cost results**

Over a 10-year time horizon, the total costs per person were AUD 3,649 ($2,533; EUR 2,085) with the Mediterranean diet and AUD 3,244 ($2,252; EUR 1,854) with the Western diet. Thus, the cost-difference was AUD 405 ($281; EUR 231).

The Mediterranean diet was associated with an increase of AUD 394 in programme costs and AUD 683 in food costs, but a reduction of AUD 901 in costs incurred for the treatment of future cardiac events.

**Synthesis of costs and benefits**

Incremental cost-effectiveness and cost-utility ratios were calculated in order to combine the costs and benefits of the two dietary regimens.

Over a 4-year time horizon, the incremental cost per cardiac death/nonfatal MI event averted with the Mediterranean diet in comparison with the Western diet was AUD 3,980 ($2,763; EUR 6,217) when only programme costs were included, AUD 10,879 ($7,552; EUR 6,217) when programme and food costs were included, and AUD 1,778 ($1,234; EUR 1,016) when programme, food, and cardiac event costs were included.

Over a 10-year time horizon, the incremental cost per QALY gained with the Mediterranean diet in comparison with the Western diet was AUD 1,013 ($703; EUR 579).

The cost-effectiveness of the Mediterranean diet remained unaltered in all the alternative scenarios considered in the sensitivity analysis. However, the cost per QALY was sensitive to the cardiac event rates, the costs of the intervention, and the time horizon of the model (range: intervention dominant to AUD 7,149 per QALY).

**Authors' conclusions**

A Mediterranean diet is highly cost-effective compared with a Western diet for patients who have already experienced their first myocardial infarction (MI).

**CRD COMMENTARY - Selection of comparators**

The rationale for the selection of the comparators was clear and was appropriate. No details of the Western diet were given, but the reader was referred to the original study. You should decide whether they are valid diet regimens in your own setting.

**Validity of estimate of measure of effectiveness**

Key clinical data on diet effectiveness came from a single randomised trial, which was identified through a systematic search of the literature. Details of the search and inclusion criteria were reported. The authors provided an in-depth description of the main characteristics of the clinical trial, which represents a high-quality source of clinical data. However, limited information on the other sources of data was provided.

**Validity of estimate of measure of benefit**

The estimation of both health benefits (cardiac events and QALYs) was modelled using the Markov model, which was appropriate given the nature of the disease. The utility weights were obtained using the time trade-off technique, which was an appropriate tool. However, no other details on the sources of the utility weights were given. Discounting was appropriately performed.
Validity of estimate of costs
Although it was stated that a societal perspective was adopted, only the direct costs were considered. Most of the costs were presented as macro-categories, but a breakdown of the cost items was given for the main intervention. The sources of the resource use and cost data were reported. The costs were discounted at an annual rate of 5%, which would appear appropriate in this instance. The price year was implicitly reported, which aids reflation exercises in other time periods. Although statistical analyses of the costs were not conducted, the impact of variations in cost items was investigated in the sensitivity analysis.

Other issues
The authors made no comparisons with the findings from other studies as this appears to have been the first economic evaluation of the Mediterranean diet. However, the Mediterranean diet compares favourably with other interventions for the secondary prevention of heart disease. The authors discussed the issue of generalisability of the study results to other settings and stated that the use of clinical data from a single trial might limit the external validity of the analysis. Further, the clinical trial was somewhat old as it referred to a cohort of patients followed from 1988 to 1992, and both the prevalence and treatment of MI might have changed over time. Similar problems of generalisability were observed on the cost side of the analysis, owing to the peculiarities of the Australian health care system in comparison with other countries. However, the results of the sensitivity analysis suggest that the study conclusions are robust, thus the analysis may be transferred to other settings without altering the results of the base-case study. Also, the prevalence of heart disease in France (from which the clinical data were taken) is lower than that in Australia and other developed countries, thus the results obtained could be seen as conservative for an Australian context. A key issue of the analysis focused on the issue of whether a diet is simply a matter of food availability, or if other factors such as lifestyle, culture, and social structure play a role in the success of the dietary regimen.

Implications of the study
The study results support the use of the Mediterranean diet in patients with a previous MI.

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