Dietitian intervention improves lipid values and saves medication costs in men with combined hyperlipidemia and a history of niacin noncompliance

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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 use of medical nutrition therapy (MNT), administered by registered dieticians, to reduce lipid values in patients with combined hyperlipidaemia (presence of hypercholesterolaemia and hypertriglyceridaemia) and a history of niacin noncompliance. The 8-week dietician intervention visits were scheduled at week 0 (70 minutes; visit 1), week 4 (70 minutes; visit 2), week 6 (30 minutes; visit 3) and week 7 (30 minutes; visit 4).

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with combined hyperlipidaemia and a history of niacin noncompliance. The inclusion criteria were:

- outpatient status;
- diagnosis of combined hyperlipidaemia, defined as a total cholesterol level of at least 6.2 mmol/L and a triglyceride level of 1.7 to 9.0 mmol/L;
- previously met (NCEP) criteria for the initiation of antihyperlipidaemic medication, that is, a low-density lipoprotein cholesterol (LDL-C) of at least 4.1 mmol/L with two or more risk factors for coronary heart disease;
- not taking antihyperlipidaemic medications;
- less than 140% of desirable body weight; and
- between the ages of 21 and 75 years.

Setting
The setting was outpatient (private practices, physicians' offices and hospital outpatient clinics). The economic study was carried out at the Department of Veterans Affairs Medical Center Lipid Research Clinic in Long Beach (CA), USA.

Dates to which data relate
The enrolment period was May 1992 to August 1993. However, the dates during which the effectiveness and resource use data were collected were not reported. The price year was 1996.
Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not carried out. Eligible patients who had had 2 to 4 individualised dietician visits over an 8-week period were retrospectively identified among a group of 73 male veterans who participated in the individualised dietary phase of a clinical trial that was carried out to assess the efficacy of a lipid-lowering drug (pravastatin). Complete data were available for 43 men who comprised the final study sample. The mean age was 60.7 (+/- 10.1) years (age range: 33 - 75).

Study design
This was a retrospective review of a case series. The patients were identified at the Department of Veterans Affairs Medical Center Lipid Research Clinic. The maximum length of follow-up was 8 weeks and the average follow-up period was 6.5 (+/- 2) weeks (range: 4 - 8). No loss to follow-up occurred since the data were derived from complete charts.

Analysis of effectiveness
The analysis of effectiveness was limited to those patients whose medical charts were complete (n=43). The primary health outcomes used in the study were the changes in total cholesterol, LDL-C, high-density lipoprotein cholesterol (HDL-C), triglycerides and body mass index. The number of patients needing antihyperlipidaemic medication was also observed.

Effectiveness results
The total cholesterol level was 6.7 (+/- 0.9) mmol/L pre-treatment and 6.0 (+/- 0.9) mmol/L post-treatment. The mean actual change was -0.75 (+/- 0.09) mmol/L (-11%), (p<0.001).

The LDL-C level was 4.4 (+/- 0.8) mmol/L pre-treatment and 3.8 (+/- 0.9) mmol/L post-treatment. The mean actual change was -0.41 (+/- 0.10) mmol/L (-9%), (p<0.001).

The HDL-C level 0.9 (+/- 0.2) mmol/L pre-treatment and 0.9 (+/- 0.2) mmol/L post-treatment. The mean actual change was 0.02 (+/- 0.02) mmol/L (4%).

The triglyceride level was 4.2 (+/- 2.1) mmol/L pre-treatment and 3.0 (+/- 1.6) mmol/L post-treatment. The mean actual change was -1.1 (+/- 0.2) mmol/L (-22%), (p<0.0001).

The body mass index was 29.9 (+/- 3.4) pre-treatment and 29.2 (+/- 3.2) post-treatment. The mean actual change was -0.7 (+/- 0.1) (-2%), (p<0.0001).

Thirty patients pre-treatment needed antihyperlipidaemic medication versus 15 post-treatment. This represented a reduction of 50%.

Clinical conclusions
The effectiveness analysis showed that the dietician-administered MNT was effective in significantly reducing total cholesterol, LDL-C and triglyceride levels.
Measure of benefits used in the economic analysis

The health outcomes were left disaggregated and no summary benefit measure was used in the economic study. The study was, in effect, a cost-consequences analysis.

Direct costs

Discounting was irrelevant since the costs were incurred during one year. The unit costs were presented separately from the quantities of resources used. The health services in the economic analysis were MNT visits and statin therapy (including monitoring). The cost/resource boundary adopted in the study was not stated. The number of MNT visits was based on the study protocol and dietician costs were estimated from actual consultation charges in a variety of ambulatory settings in southern California. Resource use and the costs of statin therapy came from a published study. The costs were updated to 1996 values using the consumer price index units for the medical care component.

Statistical analysis of costs

The costs were not treated stochastically.

Indirect Costs

The indirect costs were not considered.

Currency

US dollars ($).

Sensitivity analysis

A sensitivity analysis was performed. This included the cost of a baseline MNT visit for the 30 patients who did not participate in the study, but who attended the first visit. This was done in order to carry out a more conservative analysis and to consider two scenarios. First, very motivated patients may need only one visit. Second, low-compliance patients are likely to fail further visits. Thus, it appears to have been realistic that a proportion of patients attended only the first visit.

Estimated benefits used in the economic analysis

See the 'Effectiveness Results' section.

Cost results

The estimated total cost of MNT for one year was $11,445.00. The expected total costs of avoided statin therapy were $40,994.10. Consequently, the cost-saving (net benefit) from MNT arising from averted statin therapy was $29,549.10 ($687.19 per patient). The cost-benefit ratio was 1:3.58, which means that $1 spent on MNT saved $3.58 on statin therapy averted.

From the sensitivity analysis, when the cost of baseline MNT visits for the 30 patients who did not participate in the study and only attended the first visit were included in the calculation, the cost-saving was $27,449.10 ($638.35 per patient). The cost-benefit ratio was 1:3.03 ($1 spent on MNT saved $3.03 on statin therapy averted).

Synthesis of costs and benefits

The costs and benefits were not combined because a cost-consequences analysis was performed.

Authors' conclusions

An individualised dietician intervention reduced lipid levels, and was cost-saving because it reduced the costs of
anthyperlipidaemic medication in patients with combined hyperlipidaemia and a history of niacin noncompliance.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator, statin therapy, was appropriate because it represents the first approach for treating patients with combined hyperlipidaemia. However, this comparison was carried out only in the cost analysis. No comparator was explicitly used in the effectiveness study, where the implicit alternative was the do nothing option. It was unclear whether this represented a valid comparator. You should decide whether the two comparators represent current strategies for patients with combined hyperlipidaemia in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness used a retrospective review of a case series. This is based on a descriptive design and represents a weak source of effectiveness evidence. The retrospective nature and the lack of an explicit control group limited the internal validity of the study. The use of a prospective randomised study would have been more appropriate. The study sample was small, but statistically significant differences were observed between the baseline and final assessments. The study sample was selected from a single centre using very strict inclusion criteria. Thus, it may not be representative of the overall study population of eligible patients.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The perspective adopted in the study was unclear. It is likely that all the relevant categories of costs were included, as only the costs strictly related to MNT visits and the use of statin therapy were considered in the analysis. The authors stated that the cost-saving may have been underestimated due to the avoided hospitalisations for myocardial infarction, unstable angina, or revascularisation procedures. The cost evaluation was carried out credibly and all the steps of the analysis (unit costs and resource use data, use of a price year, adjustment for inflation, source of data) were satisfactorily described. This enhances the possibility of replicating the study in other settings. A conservative scenario was also considered in the sensitivity analysis. However, the costs were treated deterministically, and charges rather than true costs were used.

**Other issues**
The authors made extensive comparisons of their findings with those from other studies and with a prior analysis they had carried out on the same issue. In general, consistent results were observed and the authors highlighted the unique characteristics of the current analysis. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were limited to the inclusion of a conservative estimate of the costs. However, the external validity of the analysis was high due to the details provided on the cost side of the study, although caution is required when extrapolating the effectiveness results. The study enrolled patients with combined hyperlipidaemia and a history of niacin noncompliance and this was reflected in the conclusions of the analysis. The authors did not discuss any limitations of their analysis. They did, however, state that the time horizon of the present study was one year, and it was unclear whether the benefits of the MNT programme could hold over the long term.

**Implications of the study**
The study results suggested that a dietician-administered MNT intervention may successfully and efficiently improve lipid control and reduce the proportion of patients requiring statin therapy. However, the authors stressed that further studies to assess the long-term benefits of the MNT programme should be conducted.

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