Medical nutrition therapy lowers serum cholesterol and saves medication costs in men with hypercholesterolemia
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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
Medical nutrition therapy for hypercholesterolemia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Male patients with primary hypercholesterolemia.

Setting
Hospital. The economic study was performed at the Department of Veterans Affairs Medical Center Lipid Research Clinic in Long Beach, USA.

Dates to which data relate
The data for the effectiveness analysis were collected from patients under the protocol procedure between 1991 and 1994. The costs of lipid-lowering drug therapy were updated to 1995 from a 1988 cost analysis by using the Consumer Price Index. The costs for medical nutrition therapy were derived from the Referral Listing of Registered Dietitians compiled through a 1995 survey. No price year was given.

Source of effectiveness data
The estimate for final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample.

Study sample
95 male veterans with hypercholesterolemia at the clinic were retrospectively included in the study.

Study design
The study was designed as a before-and-after study performed in a single centre. The following criteria were considered for inclusion of the subjects in the study: outpatient, primary diagnosis of hypercholesterolemia, met the National
Cholesterol Education Program (NCEP) eligibility criteria for initiating cholesterol-lowering drug therapy, not taking a cholesterol-lowering drug, aged between 25 and 75 years, and had 2 to 4 visits with a dietitian over 6 to 8 weeks. Subjects received between 2 to 4 dietitian intervention visits over 6 to 8 consecutive weeks between 1991 and 1994. Medical nutrition therapy started at week 0 and follow-up visits occurred at weeks 4, 6 and 7. 21 patients were excluded from the analysis because they lacked the required information.

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only. The primary health outcomes used were: change in total cholesterol, change in low-density lipoprotein cholesterol (LDL-C), change in high-density lipoprotein cholesterol, and change in the number of patients needing lipid-lowering drugs. The latter was obtained by examining the reduction in risk in subjects eligible for anti-hyperlipidemic medications before and after dietitian intervention: LDL-C greater or equal 4.1 mmol/L with CHD and/or 2 risk factors. The risk factors considered were: high total cholesterol (6.2 mmol/L or greater), borderline-high total cholesterol (5.2 mmol/L to 6.2 mmol/L), and desirable total cholesterol (5.2 mmol/L or below). The mean age for the group was 60.9 years, the mean number of dietitian visits was 2.8 and the mean total time was 144 minutes over 6.8 weeks.

Effectiveness results
Total cholesterol was reduced by 13.4% (p<.0001). The low-density lipoprotein cholesterol was reduced by 14.2% (p<.0001) and the high-density lipoprotein cholesterol decreased by 4.4% (p<.05). Patients needing lipid-lowering drugs decreased by 51%.

Clinical conclusions
The mean change in LDL-C reduction showed a significant difference in the number of dietitian visits. In 51% of the subjects lipid drug eligibility was obviated as a result of medical nutrition therapy.

Modelling
No model was used to estimate benefits and costs.

Measure of benefits used in the economic analysis
The outcome measure used in the economic analysis was the obviation rate for lipid drug therapy. This was obtained by examining the reduction in risk in subjects eligible for anti-hyperlipidemic medications before and after dietitian intervention: LDL-C greater or equal 4.1 mmol/L with CHD and/or 2 risk factors. The risk factors considered were: high total cholesterol (6.2 mmol/L or greater), borderline-high total cholesterol (5.2 mmol/L to 6.2 mmol/L), and desirable total cholesterol (5.2 mmol/L or below).

Direct costs
The costs were measured from a health service perspective and were not discounted since the follow-up period was less than one year. Costs and quantities were reported separately. Costs included the lipid lowering drug therapies and medical nutrition therapy. The costs of lipid lowering drugs (statins and niacin) were estimated by updating to 1995 a cost analysis conducted in 1988. Costs included 80% use of statin therapy and 20% use of niacin therapy because this was the proportion spent on the two drugs at the clinic. The costs for medical nutrition therapy were derived from the Referral Listing of Registered Dietitians through a 1995 survey.

Statistical analysis of costs
Not performed.

Indirect Costs
Indirect costs were not included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
A one-way sensitivity analysis was conducted by varying dietitian consultation charges: number of dietitian visits, laboratory tests and LDL-C outcome achieved. A cost-effectiveness ratio (dollar cost per unit of change in LDL-C) was calculated. This varied from 4.66 to 7.74 for high-intensity care (4 dietician visits in 7 weeks) and 5.52 to 9.90 for moderate-intensity care (3 dietitian visits in 7 weeks). The ratio improved as the dietary visits increased from 2 to 4.

**Estimated benefits used in the economic analysis**
The reduction in the number of patients eligible for anti-hyperlipidemic medication was 34 (51%).

**Cost results**
The annualised costs of statin therapy and niacin therapy, including monitoring, were $2,648.59 and $824.25 respectively. The average cost of medical nutrition therapy was $165.

**Synthesis of costs and benefits**
Costs and benefits were not combined in a single unit of measure. The annualised cost savings of medical nutrition therapy versus lipid drug therapy were $60,561.68. The authors calculated a ratio obtained by dividing the total cost of medical nutrition therapy undertaken by all patients over the total cost of lipid drug therapy avoided (in 34 patients): $1 spent on medical nutrition therapy is equivalent to $4.28 saved on lipid drug therapy.

**Authors' conclusions**
Medical nutrition therapy in men with hypercholesterolemia leads to significant reduction in total cholesterol levels and LDL-C. This reduces the number of patients eligible for lipid drug therapy and results in substantial cost savings.

**CRD COMMENTARY - Selection of comparators**
The comparator is an established therapeutic option for the treatment of men with hypercholesterolemia.

**Validity of estimate of measure of benefit**
The measure of benefits (obviation rate of lipid drug therapy) is likely to be affected by the eligibility criteria derived from the National Cholesterol Education Program. These may vary for different countries. Patients were not randomly selected and allocated to the two alternatives by a blinded method and this may have introduced some bias into the effectiveness results that were used as a measure of benefits in the economic analysis.

**Validity of estimate of costs**
Quantities and prices were not stated. A sensitivity analysis was undertaken by varying the consultation charges and this reinforces the results. Cost savings may be underestimated since hospitalisations for myocardial infarction, unstable angina, or revascularization procedures were excluded from the analysis.

**Other issues**
Costs and benefits were not combined by calculating an appropriate cost-effectiveness ratio. The authors in fact derived a cost to benefit ratio by dividing the total costs of medical nutrition therapy over the costs saved on lipid drug therapy, which is a rather unusual approach.

**Implications of the study**
Policy makers should consider medical nutrition therapy administered by registered dietitians as an effective and cost-saving method of treating men with hypercholesterolemia. Further research is required to investigate whether a poor dietary response is related to a lesser intensity of dietary intervention or a biological resistance to diet. Also further research is recommended on dietary strategies by considering variations in the number, frequency, duration of the visits, the time interval between dietary visits, and maintenance of the normalised lipid levels.

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