Pharmacoeconomic evaluation of anti-hyperlipidemic agent fenofibrate

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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
Fenofibrate was given to patients with type IIb or type IV hyperlipidemia who had previously been taking either bezafibrate or a 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor (HMG-CoA RI). Fenofibrate doses varied from 100-200mg/day. Bezafibrate doses varied from 200-400mg/day. The pravastatin dose was 10mg/day, the simvastatin dose was 5mg/day and the fluvastatin dose was 20mg/day. The study compared patients before and after the change in medication.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had previously been diagnosed with type IIb or type IV hyperlipidemia and who were being treated with bezafibrate or HMG-CoA RI.

Setting
The setting was secondary care. The economic study was conducted in Japan.

Dates to which data relate
The dates for the effectiveness and resource data were 2000-2001. The price year used was 2000.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
Costing was carried out on the same patients who provided the effectiveness data.

Study sample
No power calculations were reported. Twenty-six patients were recruited from one hospital between 1 October 2000 and 31 January 2001. The method of selection was not stated. Eighteen patients were switched from bezafibrate to fenofibrate and 8 patients were switched from an HMG-CoA RI to fenofibrate. There was no evidence to suggest that the study sample was representative of the study population.
Study design
The study was a within group comparison in which patients who had previously been on one treatment were switched to another. See "study sample" for further details. The average time spent on the first treatment was not reported. Serum lipid levels were measured at baseline, before the treatment change, and at six months. There was no loss to follow-up.

Analysis of effectiveness
All the patients included in the study were accounted for in the analysis. The health outcomes used in the analysis were measures of the following lipids: total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglycerides (TG).

Effectiveness results
Among the patients who changed from bezafibrate to fenofibrate there was no significant change in lipid levels.

Among patients who changed from HMG-CoA RI to fenofibrate mean TC went from 219.6+/-9.8 to 223.4+/-11.8, mean LDL-C went from 122.6+/-9.3 to 150.1+/-11.5, mean HDL-C went from 44.4 +/-3.0 to 46.1 +/-3.8 and mean TG went from 263.3+/-26.6 to 180.6+/-23.2.

The increase in LDL-C was statistically significant, (p<0.05).

Clinical conclusions
Switching patients from bezafibrate to fenofibrate had no negative outcomes as regards lipid levels but the switch from HMG-CoA RI to fenofibrate increased the level of LDL-C and so might worsen long-term patient outcomes.

Measure of benefits used in the economic analysis
As no summary measure of benefit was used a cost-consequences analysis was effectively undertaken.

Direct costs
Hospital direct costs were included in the analysis. The following costs, based on actual data, were given: all costs in the internal medicine department (defined as drug related costs, diagnostic and treatment costs), all costs in other departments (defined in the same way as costs in the internal medicine department), cost of drug administration (defined as prescribing fees, formulating fees, pharmacy fees and drug information costs), drug costs in internal medicine department, and drug costs in other departments.

Discounting was not carried out as costs were incurred over a short period of time. Costs were not broken down into quantities and costs. The source of cost data on diagnostic costs, treatment costs and the drugs costs was the health insurance system. The source of the information on drug administration was the hospital. The price year was 2000.

Statistical analysis of costs
No statistical analyses were carried out.

Indirect Costs
No indirect costs were included in the analysis.

Currency
Japanese yen (Y).
Sensitivity analysis
The authors calculated a dose for fenofibrate that would stop it leading to lower costs.

Estimated benefits used in the economic analysis
The reader is referred to the effectiveness results above.

Cost results
The costs during six months before the change in medication were Y166,939 +/- 107,116.

The costs during six months after the change in medication were Y142,143 +/- 100,126, (p<0.05)

Synthesis of costs and benefits
As a cost-consequences approach was taken no synthesis took place.

Authors' conclusions
The change in medication to fenofibrate resulted in lower costs, which can be largely accounted for by the lower drug costs in the internal medicine department. The authors concluded that fenofibrate is superior to bezafibrate as it is cheaper and as effective in reducing lipids. However, they are ambiguous as to the choice between HMG-CoA RI and fenofibrate as the latter is cheaper but it does not reduce LDL-C as effectively.

CRD COMMENTARY - Selection of comparators
No explicit justification of the comparators was given. You, the user of the database, should decide if the comparator represents current practise in your own setting.

Validity of estimate of measure of effectiveness
The study design was not appropriate for the hypothesis as patients receiving two types of medication were changed to one new kind of medication. A better design would have been to have patients receiving one kind of medication being randomly assigned to either the new one or no change. There is no evidence that the study sample was representative of the study population. The patient characteristics reported were not broken down according to the initial treatment drug. There is a possibility of a time-related confounding factor with this type of study design. The authors did not assess any side effects of the medications in the study.

The increase in LDL-C was the only one that was statistically significant, but the reason for the lack of statistical significance in TC and HDL-C may have been the small sample size.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit so a cost-consequences analysis was effectively performed.

Validity of estimate of costs
The perspective was not clearly stated, but it may have been that of a third party payer. If so, it seems that the relevant cost categories were included in the analysis. The direct costs could have been broken down in a much clearer way into costs and quantities. No statistical analysis of quantities or prices was carried out. The authors calculated that if the dosage of fenobrite was increased to 439mg (the maximum permitted dose is 300mg which would have led to costs of Y155,322), there would be no reduction in costs from changing to fenofibrate. The price year was given, which helps the generalisability of the results.
Other issues
The authors did make comparisons of their results with those from other studies but did not address the issue of generalisability. The authors acknowledged that a longer-term follow-up is necessary to produce a full evaluation of the change in medication, but do not appear to be aware of the drawbacks of a before and after study compared to a randomised controlled trial. The results did not appear to be selectively presented and the authors’ conclusions reflected the scope of the analysis.

Implications of the study
The authors suggested that a study with longer follow-up would give more informative results. It could be added that a randomised design and a larger sample size would greatly improve the internal validity of the study results.

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