Using a data warehouse to monitor clinical outcomes associated with simvastatin tablet splitting

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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 prescribing of a simvastatin tablet-splitting regimen was compared with the switch from a whole to a simvastatin tablet-splitting regimen.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all patients taking simvastatin, as obtained from a data warehouse storing all prescription-related information for these patients. The authors did not provide any further information.

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

Dates to which data relate
The effectiveness data were derived from October 1998 to February 2003. The cost data were expressed in 2002/2003 prices.

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

Link between effectiveness and cost data
The costs were calculated retrospectively using the data available from the data warehouse.

Study sample
The study used all available data from a data warehouse. The authors suggested that this dataset contained all the information of an entire population. The authors emphasised that since all information available from the data warehouse was used, there was no need for a sample calculation in the analysis. No baseline demographic details of the population analysed in the study were reported. The number of patients converted from whole to half tablets was 5,683, whereas 30,152 patients started directly on the half tablet regimen. The authors seem to have used only those records where complete data on low-density lipoprotein (LDL) levels were available. The overall size of the population was not clear from the figures reported.
Study design
The study was a retrospective cohort study. The dataset contained information from four pharmacies, although their location was unclear. The analysis was carried out within one year.

Analysis of effectiveness
The primary health outcome measure was the change in LDL levels for those patients who switched from the whole to half tablet, compared with those who started directly on the half-tablet regimen. A model was developed for assessing the efficacy of tablet splitting. Owing to therapeutic guidelines, the authors performed a sub-group analysis in patients with diabetes. No baseline comparisons between the groups were presented.

Effectiveness results
For those patients who switched from the whole to the half-tablet regimen, the LDL levels dropped an average of 15 mg/dL after one year to 107.6 mg/dL.

Patients who started the half-tablet regimen directly did not require any dose adjustment since the LDL levels remained the same after one year.

Overall, patients with diabetes performed well after changing their regimen, with 51% at normal levels of 100 mg/dL. However, 12% of patients experienced an adverse outcome with an LDL level greater than 100 mg/dL.

Clinical conclusions
The authors suggested that switching from whole simvastatin tablets to a tablet-splitting regimen seems to be an effective alternative with little associated risk.

Measure of benefits used in the economic analysis
As the outcome results suggested that both regimes were similar, the analysis should be considered a cost-minimisation analysis.

Direct costs
Only the direct costs of simvastatin tablets were included in the costing analysis. It would seem that the perspective adopted in the analysis was that of the patient. Resource use, in terms of quantities of split tablets, was reported separately from the costs. No detailed information on the unit costs and their source was provided. The costs were expressed in 2002/2003 prices. Discounting was not necessary since the costs were accrued during one year.

Statistical analysis of costs
The costs were treated as point estimates. The standard deviation was used as a measure of variability.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
The authors stated that the data warehouse included the entire population of interest. Hence, a sensitivity analysis was
not needed to explore uncertainty.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total costs for the entire population were $721,779 for split tablets and $1,067,065 for a course of whole tablets. The difference of $345,286 favoured the simvastatin tablet-splitting alternative.

**Synthesis of costs and benefits**
The costs and effects were not combined as the analysis was considered a cost-minimisation study.

**Authors' conclusions**
The authors suggested that a policy of simvastatin tablet-splitting may be an effective and cost-saving alternative to a policy of prescribing whole tablets.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator was clear. The investigators explored the effect of switching from whole tablets to tablet splitting in a population taking simvastatin. The current concern about the issue justified the claim that research in the area is needed before recommending adoption. The comparator used appears to have represented current practice in the authors' settings. Readers should decide whether this represent current practice in their own setting.

**Validity of estimate of measure of effectiveness**
Changes in LDL levels were defined as the primary outcome measure. This choice of outcome seems to have been justified on medical grounds. The study design might have benefited from a better explanation by the authors. The investigators claimed that an entire population was available in the dataset. However, no baseline demographic characteristics of the dataset were provided, which made it very difficult to identify the population of interest. It was unclear from the text how the numbers of patients in each group were calculated. It appears from the analysis that only patients with complete data on LDL levels have been included. Although it seems logical to calculate LDL levels only for those patients with complete data, this introduces noise in the results as the final numbers for analysis are significantly lower than the original sample reported in the abstract of the article. It is likely that those excluded had a different distribution of baseline characteristics, thus the analysis of complete cases could be biased. For the same reason it was not possible to say whether the groups were comparable. These issues might have influenced the internal validity of the analysis.

**Validity of estimate of measure of benefit**
As both regimes showed similar outcomes between the groups, the analysis was considered to be a cost-minimisation analysis. Please see the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
Only the costs of the tablets were included in the analysis. The perspective adopted seems to have been that of the patient and, from this perspective, it is likely that the relevant categories have been included the analysis. Besides, as both groups received the same drug, any category omitted is expected to be similar in both groups and will tend to cancel out. Resource use was reported separately from the total costs, which is good practice as it helps in the understanding of the costing analysis. However, no information on the unit costs and its source were reported in the paper, and this may influence the internal validity of the analysis.
Other issues
The authors reported the results of similar studies in the introduction of the paper. However, they did not directly compare their current results with the findings of such studies. The results of the study were not presented selectively. The issue of generalisability was addressed in the 'Discussion' section. The authors acknowledged that similar results may be found in populations with similar baseline characteristics. They also stated "it is unknown whether the effect on the LDL was due to the tablet splitting or to some other undiscovered cause".

Implications of the study
Tablet splitting seems an effective mechanism for managing health care organisations, and it potentially saves substantial patient costs with little risk associated. Further research is needed to determine whether this can be generalised to other risk sub-populations, like diabetes.

Source of funding
None stated.

Bibliographic details

Other publications of related interest


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