Use of valsartan for the treatment of heart-failure patients not receiving ACE inhibitors: a budget impact analysis

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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 addition of valsartan to usual care for the treatment of heart failure (HF) in patients not taking angiotensin-converting enzyme (ACE) inhibitors because of side effects or contraindications. Valsartan was given at a starting dose of 40 mg twice daily and titrated to a target dose of 160 mg twice daily. Usual care might include diuretics, digoxin or beta-blockers for more than 2 weeks.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of adult patients with HF who were not receiving ACE inhibitors because of side effects or contraindications.

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

Dates to which data relate
The effectiveness data were derived from studies published between 2001 and 2005. The cost and resource use data were derived from sources published in 2002 and 2003. The price year was 2001.

Source of effectiveness data
The clinical and epidemiological data used in the analysis were:

age-group distributions of patients,
HF prevalence,
the proportion of HF patients not on ACE inhibitors,
the expected rate of HF hospitalisations among patients not on ACE inhibitors and not receiving valsartan,
the mean length of stay for HF hospitalisation,
the expected reduction in HF hospitalisations among patients not on ACE inhibitors and receiving valsartan, and
the expected reduction in mean length of stay for HF hospitalisations among patients not on ACE inhibitors and receiving valsartan.

**Sources searched to identify primary studies**
The clinical data were derived from different published sources. For example, age-group distributions of patients were derived from US Census data. The effectiveness of valsartan came from a clinical trial (Maggioni et al. 2002, see 'Other Publications of Related Interest' below for bibliographic details). The proportion of HF patients not on ACE inhibitors came from different studies, including a review of 37 studies.

**Methods used to judge relevance and validity, and for extracting data**
The authors did not report any explicit criterion to identify the primary studies. Thus, the primary studies might have been identified selectively rather than through a systematic review of the literature. However, the main source of the effectiveness data, the relative risk reduction in hospitalisations due to valsartan, was obtained from a randomised controlled trial that was selected on the basis of criteria for internal validity.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.

**Direct costs**
The analysis of the costs was carried out from the viewpoint of a health plan. The categories of costs included in the study were HF-related hospitalisations and valsartan. The costs of other medications were not considered. The unit costs and the quantities of resources used were not presented separately. Hospitalisation costs (mean costs and mean length of stay) were estimated from information based on >19 million discharges, representing more than 50% of all discharges from short-term, general, non-federal US hospitals. Drug costs were estimated on the basis of average wholesale prices. No adjustments for discounts, rebates, or co-payments were made in the analysis. Discounting was not relevant as short-term costs were evaluated. The price year was 2001.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The productivity costs were not considered in the economic analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
A univariate sensitivity analysis was carried out to assess the robustness of cost-savings to variations in HF prevalence rate, the relative risk reduction, the proportion of patients not receiving ACE inhibitor therapy, alternative plan sponsor distributions, and the proportion of urban versus rural hospitals. Alternative values were based on authors' opinions.

**Estimated benefits used in the economic analysis**
No benefits were estimated.
Cost results
In a hypothetical health plan with 250,000 members, about 1,207 individuals would suffer from HF. Of these, 50% (603) would not take ACE inhibitors. The mean annual cost of HF-related hospitalisations associated with these patients was $1,905,825.

The expected savings in HF-related hospitalisation cost due to fewer hospitalisations among patients not on ACE inhibitors but receiving valsartan were $1,083,938.

The expected savings due to reduced length of hospital stay among patients not on ACE inhibitors and receiving valsartan were $221,364.

The annual cost of valsartan treatment was $629,472.

Overall, the net annual cost-savings due to valsartan treatment were $675,830.

The sensitivity analysis showed that most of the changes observed in the cost-savings associated with valsartan were in the expected direction. For example, assuming the prevalence of HF to be twice that of the base-case substantially increased the projected cost-savings due to valsartan therapy (almost doubled to $1,350,617). Halving the prevalence was associated with a reduction in the annual projected cost-savings ($342,185). The most interesting result of the sensitivity analysis was the assumption about the plan sponsor distribution. Assuming that 100% of the plan employees were covered by Medicaid, commercial insurance, or Medicare changed the valsartan-therapy associated annual cost-savings to $727,218, $902,427 and $609,508, respectively.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was carried out.

Authors’ conclusions
The addition of valsartan therapy to usual care resulted in net cost-savings in heart failure (HF) patients not receiving angiotensin-converting (ACE) inhibitors as a result of reduced hospitalisations and length of hospital stay. Valsartan therapy was cost-saving regardless of patient, treatment, plan sponsor and hospital characteristics.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear since usual care was compared with the new therapy for HF. Usual care was described. The exclusion of ACE inhibitors was the rationale for the study. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The clinical data were derived from published studies, although it was not stated whether a systematic review of the literature was undertaken to identify these studies. Details such as the inclusion criteria and methods of synthesis were not reported. The treatment effect for valsartan was derived from a clinical trial, which represents an appropriate source of clinical data. However, the authors noted that compliance, in the context of a clinical trial, might not be as high as compliance in a real world setting. Other data were obtained from a published review. However, since information on the other sources of data was limited, it was not possible to assess the validity of the clinical data.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The analysis of the costs was consistent with the perspective stated in the study. Appropriate sources of costs were used. Hospitalisation costs were presented as a macro-category, which is consistent with the viewpoint of the health plan. Statistical analyses were not carried out, but the impact of changes in both clinical and economic factors on the total costs was extensively investigated in the sensitivity analysis. The price year was reported, thus facilitating reflation exercises in other time periods. A large database was used to derive the hospital costs, thus making the analysis representative of the US setting. The authors noted that discounts and rebates were not considered, so the estimated additional costs of valsartan therapy might have been overestimated. However, physician visits potentially necessary for valsartan were also not included. In general, the cost analysis was limited to hospitalisation costs (plus valsartan), but the inclusion of other direct costs or indirect costs might have been important, as the authors acknowledged.

Other issues
The authors did not make extensive comparisons of their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. However, the sensitivity analysis implicitly investigated the external validity of the analysis since the use of alternative values was tested. The study referred to a specific sub-group of patients with HF (those not on ACE inhibitors) and this was reflected in the authors' conclusions. The authors pointed out some potential limitations of their analysis, which have been reported already.

Implications of the study
The study results support the use of valsartan therapy for the treatment of patients with HF not on ACE inhibitors.

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Other publications of related interest
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Subject indexing assigned by NLM

MeSH
Aged; Angiotensin II Type 1 Receptor Blockers /economics /therapeutic use; Angiotensin-Converting Enzyme Inhibitors /economics /therapeutic use; Budgets /methods /trends; Cost-Benefit Analysis; Heart Failure /drug therapy /economics; Hospitalization /economics /statistics & numerical data; Humans; Models, Economic; Tetrazoles /economics /therapeutic use; Time Factors; Valine /analogs & derivatives /economics /therapeutic use; Valsartan

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