The cost effectiveness and cost utility of valsartan in chronic heart failure therapy in Italy: a probabilistic Markov model

Pradelli L, Iannazzo S, Zaniolo O

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.

CRD summary
This study examined the cost-effectiveness of valsartan in patients aged 45 years or older, who had chronic heart failure, with a low (<40%) left ventricular ejection fraction. Valsartan was likely to be an effective and economically attractive addition to therapy for these patients, especially those not receiving angiotensin-converting enzyme inhibitors, those in New York Heart Association classes III and IV, and those not receiving beta-adrenoceptor antagonists. The methods were good and well reported, enhancing the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study examined the cost-effectiveness of adding valsartan to standard therapy for patients who were aged 45 years or older and had mild-to-severe chronic heart failure (CHF), with a low (<40%) left ventricular ejection fraction (LVEF).

Interventions
The two strategies were valsartan plus standard care versus standard care alone for the treatment of CHF and low LVEF.

Location/setting
Italy/primary and secondary care.

Methods
Analytical approach:
The analysis was based on a probabilistic Markov model, with a 10-year horizon. The authors stated that the perspective was that of the Italian Health Service (IHS).

Effectiveness data:
The key clinical endpoint was the treatment efficacy, which was the reduction in hospitalisations (due to the worsening of heart failure) plus the improvement in disease symptoms. These data were derived from the Valsartan in Heart Failure Trial (Val-HeFT), which analysed 5,010 patients with New York Heart Association (NYHA) classes II, III, or IV heart failure. There were 2,511 patients (2007 men; mean age 62.4 years) in the valsartan group and 2,499 patients (2000 men; mean age 63 years) in the control group. The length of follow-up was 23 months. A key assumption was that the efficacy of treatment was zero from the 24th month to the end of the simulation. Other inputs, such as the prevalence of heart failure and mortality by NYHA class, were derived from country-specific databases.

Monetary benefit and utility valuations:
The utility values were from quality of life estimates from patients with CHF and low LVEF collected during a large published study, of the general English population, that used the Short Form (SF-36) Health Survey. Regression models were used to convert the SF-36 results into utility weights.

Measure of benefit:
Life-years (LYs) and quality-adjusted life-years (QALYs) were the summary benefit measures and they were
discounted at an annual rate of 3.5%.

Cost data:
The economic analysis considered the costs of drugs and heart failure hospitalisations. The drug costs were based on the maximum price to the IHS for a pack of 28 160mg tablets and the mean dose used in the Val-HeFT. The cost of hospitalisations was based on diagnosis-related group reimbursements at a national level. The costs were in Euros (EUR) and were discounted at an annual rate of 3.5%. The price year was 2007.

Analysis of uncertainty:
A probabilistic sensitivity analysis was undertaken on all the inputs, using published confidence intervals or a range of ±10%. Subgroup analyses were carried out to consider various demographic and clinical factors.

Results
The expected LYs were 2.300 with valsartan and 2.287 with standard therapy. The QALYs were 1.674 with valsartan and 1.659 with standard therapy. The costs were EUR 6,289 with valsartan and EUR 6,843 with standard therapy. Valsartan was the dominant strategy as it was more effective, by 0.013 LYs and 0.015 QALYs, and less expensive, by EUR 554, compared with standard therapy alone.

Valsartan remained the dominant strategy in all subgroup analyses except three: the incremental cost per QALY gained with valsartan was EUR 36,500 in patients receiving angiotensin-converting enzyme (ACE) inhibitors; EUR 21,240 in NYHA class II patients; and EUR 129,200 in patients receiving β-adrenoceptor antagonists.

The probabilistic analysis showed that valsartan had a 60% likelihood of being dominant and a 67% chance of being cost-effective at a threshold of EUR 30,000 per QALY.

Authors' conclusions
The authors concluded that valsartan was likely to be an effective and economically attractive addition to therapy for patients with heart failure, especially for those who were not on ACE inhibitors, those in NYHA classes III and IV, and those who were not receiving β-adrenoceptor antagonists.

CRD commentary
Interventions:
The comparators were appropriately selected as the new drug was added to the current therapy for CHF patients. No clear description of the standard therapy was provided.

Effectiveness/benefits:
The clinical evidence was from selected studies. Most of it was from a randomised controlled trial, with a very large sample, and these are generally considered to be valid sources of evidence due to their design. Other data were from country-specific databases. The key assumption on the duration of treatment efficacy was explicitly stated and was necessary as no additional data were available. It is not clear whether this could have biased the results in favour or against valsartan. The key information on the design and results of the trial was provided. The approach used to derive and then calculate the utility valuations was appropriately described. QALYs and LYs are validated benefit measures, which are also comparable with the benefits of other health care interventions.

Costs:
The economic analysis was consistent with the perspective in terms of both cost categories and the data sources. Resource consumption reflected the pattern of use in the clinical trial. The price year was clearly presented. Some key data on the unit costs and quantities of resources used were reported. The costs were treated stochastically and appropriate distributions were used.

Analysis and results:
The analysis was well conducted and an incremental approach was used to synthesise the costs and benefits, where appropriate. This allowed the identification of the dominant strategy. The issue of uncertainty was satisfactorily investigated in a well-conducted probabilistic analysis. The results were clearly presented and discussed well.
probabilistic Markov model, with individual patient simulations, was a good basis for the analysis.

Concluding remarks:
The methods were good and the study was generally well reported, which enhances the validity of the authors’ conclusions.

Funding
Supported by a grant from Novartis Farma, Origgio, Italy.

Bibliographic details

PubMedID
19929036

DOI
10.2165/11315730-000000000-00000

Original Paper URL

Indexing Status
Subject indexing assigned by NLM

MeSH
Age Factors; Aged; Antihypertensive Agents /economics /therapeutic use; Chronic Disease /drug therapy /economics; Computer Simulation; Cost-Benefit Analysis /methods; Drug Costs; Female; Heart Failure /drug therapy /economics /mortality; Hospital Costs; Humans; Italy; Male; Markov Chains; Middle Aged; Models, Statistical; Quality of Life; Quality-Adjusted Life Years; Sex Factors; Tetrazoles /economics /therapeutic use; Valine /analogs & derivatives /economics /therapeutic use; Valsartan

AccessionNumber
2201000245

Date bibliographic record published
07/07/2010

Date abstract record published
29/09/2010