Cost-effectiveness modeling of intrathecal baclofen therapy versus other interventions for disabling spasticity

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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.

CRD summary
The objective was to assess the cost-effectiveness of intrathecal baclofen as a first treatment in the medical management of spasticity, in France. The authors concluded that initial baclofen could be cost-effective compared with usual care. The cost and effectiveness estimates were poorly reported, making the validity of the results unclear. No attempt was made to control for confounding variables and the data were from limited observational evidence. The results should be used with caution.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to assess the cost-effectiveness of first-line intrathecal baclofen for the medical management of disabling spasticity caused by any neurological disease, in France.

Interventions
The intervention was intrathecal baclofen as a first treatment. Followed by one of various sequences of baclofen dose adjustment and then pump explantation if necessary; oral treatment; neurosurgery; nursing; or focal spasticity treatment, if treatment failed.

The comparator was physical treatment, followed by oral treatment, if initial treatment failed. The next option was one of three: neurosurgery followed by nursing; intrathecal baclofen, with dose adjustment, if necessary; or focal spasticity treatment followed by neurosurgery, if necessary. Nursing was the last option in this strategy.

Location/setting
France/secondary care.

Methods
Analytical approach:
Decision trees were developed to assess the cost-effectiveness of the two treatment strategies for the management of spasticity. The outcomes were assessed over two years. The authors did not state the study's perspective.

Effectiveness data:
The key effectiveness parameter was the success rate over two years. Success was defined as increased patient and caregiver satisfaction, assessed on the 5-point goal attainment scale (GAS), plus at least a 1-point decrease in the patient's Ashworth score. The transition probabilities for treatment success, with each subsequent treatment, were from an analysis of a retrospective survey from one hospital experienced in delivering rehabilitation. Patients achieving treatment success continued therapy for up to two years. Patients who failed to respond after six months changed to the next therapy.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The health benefit was measured by the success rate for each treatment strategy.

Cost data:
The analysis covered the costs for each treatment, including physician visits, nursing, hospitalisations, transport, treatment acquisition, and treatment for complications. The costs were based on a French retrospective cost survey and were reported in 2006 Euros (EUR).

Analysis of uncertainty:
Probabilistic sensitivity analysis was used to assess the impact of overall uncertainty in the cost and effectiveness parameters on the results. The probability distributions assigned to the model parameters were based on retrospective patient databases and validated by an expert panel. The analysis used 5,000 Monte-Carlo simulations.

Results
Over two years intrathecal baclofen was associated with a success rate of 78.7%, compared with 59.3% for usual care (p<0.001). Baclofen cost EUR 59,391, compared with EUR 88,272 for usual care (p<0.001).

Baclofen was the dominant strategy, providing greater effectiveness at a lower cost. The average cost per success was EUR 75,204 for baclofen and EUR 148,822 for usual care (p<0.001).

Authors' conclusions
The authors concluded that initial baclofen could be a cost-effective strategy, compared with usual care.

CRD commentary
Interventions:
The intervention was clearly described, along with the treatment strategy that followed. An appropriate comparator, standard care, was used. The different stages of standard care were clearly described, and were stated to be based on the established treatment pattern in France.

Effectiveness/benefits:
The effectiveness measure was clearly stated, but the description of the data was generally poor. No details of the retrospective survey were reported; the values for the effectiveness parameters were not reported; and the standard deviations used to derive probability distributions were not reported. It was not clear if the survey was the best available evidence; the authors stated that no head-to-head trials were available, but they did not report a comprehensive search for evidence. Due to these reporting limitations, it is not clear if the effectiveness estimates were appropriate, so the validity of the effectiveness outcomes is unclear.

Costs:
The costs indicated that a health service provider perspective was adopted. The cost categories were clearly stated and seem to have been appropriate for this perspective. Few details of the source used to derive costs were reported. Only the aggregate costs for each treatment were given, with no resource use and no individual unit costs. This reduces the transparency of the cost data. No discounting of those costs and benefits accrued beyond the first year appears to have been conducted.

Analysis and results:
The decision trees were clearly described, with a diagram. A full incremental analysis was not conducted – mean cost-effectiveness ratios were presented; these are less informative than incremental cost-effectiveness ratios. Due to a lack of data, the analysis had to use retrospective observational data, rather than randomised patient data. This increased the risk of selection bias. No attempt to control for any confounding variables appears to have been conducted, which further increased the risk of bias. Appropriate sensitivity analysis was conducted, but the distributions were not described. The cost and effectiveness estimates were from French sources, so care should be taken when attempting to generalise the results to other settings.

Concluding remarks:
The cost and effectiveness estimates were poorly reported, making the validity of the results unclear. No attempt was made to control for confounding variables, and the data were from limited observational evidence. The results should be
used with caution.

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