Functional benefits and cost/benefit analysis of continuous intrathecal baclofen infusion for the management of severe spasticity

Sampson F, Hayward A, Evans G, Morton R, Collett B

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 use of intrathecal baclofen infusion in the treatment of severe spasticity.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with severe spasticity.

Setting
The setting was secondary care. The economic analysis was carried out in the UK.

Dates to which data relate
The effectiveness data were gathered from studies published between 1987 and 1997. Key resource data were gathered from two sources published in 1995 and 1999, and from semi-structured interviews with clinicians. The price year was 1999.

Source of effectiveness data
The effectiveness data were derived from a review of published studies.

Modelling
The authors did not report that a decision analytic model was created to simulate the costs and the health outcomes assigned to each strategy, although it is likely that some form of model was used to synthesis the data.

Outcomes assessed in the review
The parameters assessed in the systematic review and used in the analyses were:

- the proportion of bed-bound patients becoming able to sit in a wheelchair;
- the proportion of patients who had severe difficulty sitting in a wheelchair becoming able to sit comfortably;
- the proportion of wheelchair users improving their wheelchair mobility;
the proportion of wheelchair users improving their ability to transfer;
the proportion of wheelchair-bound patients becoming ambulatory;
the proportion of ambulatory patients improving their ability to walk;
the proportion of patients improving their ability to perform activities of daily living (ADL);
the proportion of improved ease of nursing care;
the proportion of patients with skin integrity problems who showed improvements in these symptoms; and
the proportion of reduction in spasm-related pain.

Study designs and other criteria for inclusion in the review
All identified trials and reviews of the use of intrathecal baclofen were included if the study sample considered had one of several conditions. More specifically, cerebral palsy, multiple sclerosis, spinal chord injury, traumatic brain injury, or hypoxic brain injury. The authors also specified that the trials must include more than one patient and the average follow-up period must be at least 6 months.

Trials in which only measurements of patient impairment were recorded (e.g. Ashworth score, spasm score, or reflex score) were not included.

Sources searched to identify primary studies
MEDLINE, EMBASE, DARE and databases of the Cochrane Collaboration were searched from 1984 to 1999 to identity primary studies.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Seventeen studies were included in the review.

Methods of combining primary studies
The results of the individual primary studies were combined using a meta-analysis.

Investigation of differences between primary studies
The authors did not investigate any differences between the primary studies.

Results of the review
Approximately two thirds of patients who were bed-bound because of their spasticity could be seated in a wheelchair following continuous intrathecal baclofen infusion.

A small proportion of patients who were wheelchair-bound became able to walk with assistance (11%).
Approximately one third (40%) of ambulatory patients had some improvement, while a small proportion (9%) experienced a deterioration in their ability to walk.

Significant reductions in spasm-related pain were noted (89%). Complete resolution of pain was reported by many of these patients, although some had residual neurogenic pain.

The reduction in spasticity led to improvements in ability to transfer (96%) and ease of nursing care (92%) in the majority of patients.

**Measure of benefits used in the economic analysis**
The benefit measure was the number of quality-adjusted life-years (QALYs) gained. Baseline health-related QOL estimates were assessed using the EQ-5D (EUROQOL, see ‘Other Publications of Related Interest’ for bibliographic details). Each dimension of the EQ-5D was scored from 1 (best possible state) to 3 (worst possible state). Improvements expected in each of the five dimensions of the EQ-5D, and the proportion of patients who would be likely to experience these benefits were estimated from the review and supported by clinical opinion.

Health-related QOL was estimated for three categories of patients with different levels of disability. Category one was bed-bound patients experiencing severe spasm-related pain. Category two was bed-bound patients who were not in pain. Category three was wheelchair users with moderate spasm-related pain.

The benefits were discounted at an annual rate of 6%.

**Direct costs**
A hospital perspective was adopted. The categories of costs included in the analysis were pre-screening evaluation, test dose procedure, implantation procedure, other costs and follow-up costs. The pre-screening costs were for neurosurgeon time and outpatient visits. The cost of the test procedure included lumbar puncture, lumbar catheter, hospitalisation, drug cost, physiotherapist and nursing time. The cost of the implantation procedure covered the pump, catheter, drugs and inpatient stay. Other costs comprised the costs of tests, pathology, radiology and microbiology. Potential transport costs were not included. Key cost elements were identified from the literature and from semi-structured interviews with clinicians. The unit costs were derived from 1999 data from three centres within the UK in which the operation was performed. The unit costs were reported but the quantities of resources used were not. The total costs of treatment were estimated for the 5-year period and were discounted at an annual rate of 6%.

**Statistical analysis of costs**
No statistical analysis of the costs was performed.

**Indirect Costs**
The indirect costs were not included.

**Currency**
UK pounds sterling (£). The conversion rate was $1 = 0.654.

**Sensitivity analysis**
One-way sensitivity analyses were performed to evaluate the effects of varying cost estimates. A threshold sensitivity analysis was performed to examine the annual gains in QALYs required to provide specific cost-effectiveness ratios between 5,000 and 25,000 per QALY.

**Estimated benefits used in the economic analysis**
The baseline QOL value (EQ-5D score) was -0.594 (33333) in category 1, -0.208 (33313) in category 2 and 0.079 (23322) in category 3.

The adjusted QOL improvement associated with continuous intrathecal baclofen infusion was 0.50 in category 1, 0.27 in category 2 and 0.43 in category 3.

Cost results
The cost of continuous intrathecal baclofen infusion was approximately 11,700 ($17,890) per annum for the assessment, test dose and implantation procedure. The follow-up costs were between 550 and 1,160 ($887 - $1,174) per annum.

The total discounted cost over a 5-year period was 15,420 ($23,578).

Synthesis of costs and benefits
The cost per QALY gained ranged between 6,900 and 12,7900 ($10,550 - $19,560).

Authors' conclusions
In carefully selected patients who have not responded to less invasive treatments, continuous intrathecal baclofen infusion is likely to lead to worthwhile functional benefits. Continuous intrathecal baclofen infusion has an acceptable cost-effectiveness ratio compared with other interventions that are funded by the health service.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator (no treatment) was clear. You should decide whether it represents a currently used approach in your own setting.

Validity of estimate of measure of effectiveness
It appears that a systematic review of the literature was undertaken. The sources searched for primary studies and the inclusion criteria were reported. However, the criteria used to ensure the validity of the primary studies were not reported, nor was the method used to judge the relevance and validity of the data. The impact of differences between the primary studies was not investigated, which limits the validity of the meta-analysis. Sensitivity analyses were not performed on effectiveness outcomes. In addition, the number of patients included in each of the primary studies was small (between 6 and 70 patients). However, the authors reported that the range of benefits and the proportion of patients who may benefit were consistent across the studies. More detailed reporting on the methods of the review would enhance the reliability of the results obtained.

Validity of estimate of measure of benefit
The QOL estimates were not derived from preferences of patients with severe spasticity but from the general population, using the EQ-5D tool. In addition, it appears that the authors "calculated" adjusted QOL improvements on the basis of clinicians' opinion. These facts are highlighted as many experts feel that they limit the relevance of the QALY estimates and, hence, the cost-effectiveness results. From whom preferences should be elicited is a topic regularly under debate. The authors justified the time horizon (5 years). A threshold sensitivity analysis was performed on QALY estimates, which was relevant for the study question. Discounting was relevant and was appropriately performed.

Validity of estimate of costs
All the categories of costs relevant to the perspective adopted appear to have been included in the analysis. Potential savings arising from reductions in hospitalisation, orthopaedic surgery and nursing care were not included, and no justification was provided for their exclusion. This might have led to the underestimation of the cost-effectiveness ratio.
of continuous intrathecal baclofen infusion. Details of the unit costs and the quantities of resources used were not reported separately, and this limits the possibility of replicating the study in other settings. The price year was reported. Statistical tests were not carried out and the costs were treated deterministically. Sensitivity analyses were performed on the costs, and the authors justified the ranges used. Discounting was performed since the follow-up period was longer than 2 years.

Other issues
The authors did not compare their results with those from other published studies. They also did not address the issue of the generalisability of the study results to other settings. The results were not reported selectively and the conclusions reflected the scope of the study. The authors highlighted some limitations of their study. For example, the exclusion of potential savings associated with reductions in hospitalisations, surgery and nursing care, and the drawbacks of the EQ-5D.

Implications of the study
The authors would appear to be in favour of continuous intrathecal baclofen infusion in patients who have not responded to less invasive treatments and who are bed-bound or wheelchair-bound because of severe spasticity. They recommended that future research should measure functional benefits in different patient groups and collect primary health-related QOL data, ideally within the context of large national trials.

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Other publications of related interest

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MeSH
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