The effectiveness of intrathecal baclofen in the management of patients with severe spasticity

Authors' objectives
To identify and review the evidence-base for the use of intrathecal baclofen in the treatment of spasticity, and to outline the potential cost implications of providing the treatment for all patients who may benefit.

Searching
MEDLINE, EMBASE, DARE and The Cochrane Library were searched using the terms 'Intrathecal' and 'Baclofen'. Reference lists of review articles and of the included papers were also scanned. For the purpose of the economic analysis, references with the keywords 'costs' or 'economic' were also obtained.

Study selection
Study designs of evaluations included in the review
There were no restrictions on study design but trials must have included more than one patient and had an average follow-up period of at least six months to be eligible for inclusion.

Specific interventions included in the review
Continuous intrathecal baclofen infusion (CIBI). In the majority of studies the Medtronic infusion system was used. No dose information was reported.

Participants included in the review
Adults and children whose spasticity was refractory to other treatments for the management of spasticity, including physical and oral treatments; patients who had experienced unacceptable side-effects with oral drug therapy. Patients with the following conditions were eligible for inclusion: cerebral palsy, multiple sclerosis, spinal injury, traumatic brain injury and hypoxic brain injury.

Outcomes assessed in the review
Trials measuring patient outcomes in terms of function, quality of life, pain, subjective patient or carer report of effectiveness, or health service use, were eligible for inclusion.

The majority of studies used a 5-point scale described by Ashworth (see Other Publications of Related Interest no.1), or a modified version (see Other Publications of Related Interest no.2), to measure the level of spasticity. The Penn spasm score was also used. A large variety of measures relating to function or quality of life were used, these included: outcomes related to mobility, e.g. ability to sit out of bed and ability to transfer; activities of daily living (ADLs); level of nursing; and pain. Most studies did not use formal scales to measure these outcome.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
No formal assessment of validity was undertaken.

Data extraction
A standard data form was used to extract information from the included papers. The authors do not state how many of the reviewers performed the data extraction. Specific data was extracted on: inclusion and exclusion criteria; description of patients; intervention and duration of follow-up; results; and comments.
Methods of synthesis
How were the studies combined?
A narrative synthesis was undertaken. Where possible, the authors also calculated the best estimates available of the percentage of patients likely to benefit, and rounded these to the nearest 10%.

How were differences between studies investigated?
The studies were discussed according to the origin of spasticity, i.e. cerebral or spinal, where it was possible to do so.

Results of the review
Twenty-six studies (n=494) and one meta-analysis (see Other Publications of Related Interest no.3) met the criteria for inclusion. Of the 26 studies, one was a randomised controlled trial and the remaining 25 trials were uncontrolled, open, follow-up studies.

The quality of evidence demonstrating the effectiveness of CIBI is generally poor, consisting almost entirely of small, open, uncontrolled follow-up studies with subjective outcome measures, which failed to report results separately in different patient groups.

The following points are a summary of the main findings:

1. Patients with very severe spasticity, who are bed-bound and difficult to nurse, are likely to benefit from being able to sit out of bed; nursing care is also likely to be easier. Such patients are very unlikely to have improvements in ADLs.

2. Patients who use wheelchairs, but have great difficulty in being seated in the chair, are likely to benefit by being able to sit much more comfortably.

3. Patients with a reasonable degree of remaining function may show some improvements in their ability to perform important functions such as transfers, feeding, dressing or wheelchair mobility. Most studies do not quantify the level of improvement, so it is difficult to judge the extent of the improvement from the literature.

Cost information
The cost of the pump and implantation procedure is estimated at around £11,800, with further annual costs of £500 to £900 for follow-up and refill. Use of threshold analysis suggested that, assuming 5 years of benefit are obtained, a benefit of around 0.16 quality-adjusted life-years would equate to a cost-utility ratio of £20,000.

Authors’ conclusions
The authors’ conclusion appears to state that despite the methodological drawbacks, the range of benefits and the proportion of patients benefiting were reasonably consistent across studies. However, the use of CIBI should only be considered after patients have undergone a full assessment to ensure any potential underlying aggravating factors have been eliminated, and all other potential avenues for treatment have been explored.

CRD commentary
Overall, the quality of this review was fair and the authors posed a well-defined review question. The inclusion and exclusion criteria were clearly stated and a comprehensive search was undertaken, although there was no assessment of publication bias. The authors failed to report on a number of methodological criteria. Firstly, they did not report any details regarding the process of, or the number of reviewers who undertook, the selection of studies. In addition, there was no formal assessment of study validity and the number of reviewers who carried out the data extraction was not reported. The authors provided sufficient details of the study, and the narrative synthesis of the results was appropriate. The authors’ conclusion are suitably cautious given the methodological limitations of the data, and they report a number of options for purchasers.

Implications of the review for practice and research
Practice: The authors identify a number of possible options for purchasers and commissioners within the review.

Research: The authors state that large, multicentre, randomised controlled trials with long-term follow-up and appropriate outcome measures, along with good-quality information on costs, are required to progress the current state of knowledge.

Bibliographic details

Other publications of related interest

Indexing Status
Subject indexing assigned by CRD

MeSH
Baclofen /therapeutic use; Muscle Relaxants, Central /therapeutic use; Muscle Spasticity /drug therapy

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.