

## ***Executive summary***

# **Intrathecal pumps for giving opioids in chronic pain: a systematic review**

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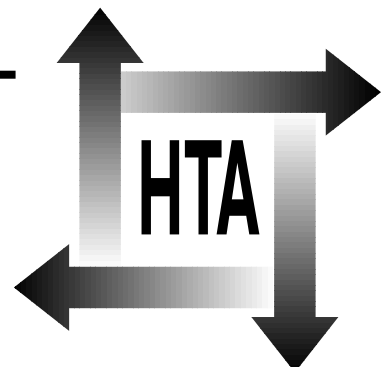
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**Health Technology Assessment  
NHS R&D HTA Programme**





## Executive summary

### Background

The use of intrathecal pumps for giving opioids in the treatment of chronic pain first started in the late 1970s. At that time it was appreciated that the spinal cord was important in pain transmission and that targeting the delivery of opioids directly to the spinal cord by using implanted intrathecal pumps could result in better pain control.

Throughout the 1980s and 1990s there were improvements in intrathecal drugs and pump systems. A wide variety of systems were in use, ranging from the simple catheter to the more sophisticated and expensive totally implantable, externally programmable pump. They were used for cancer and non-cancer patients who had pain that was resistant to conventional therapy. The aim was better pain control with fewer adverse effects than conventional routes of opioid administration such as tablets or injections. Throughout this time a wide body of clinical experience was reported in the literature.

This type of treatment is invasive, prone to side-effects and complications, costly and requires a large amount of technical support. However, there are some patients in whom all conventional pain-relieving therapies have failed and in whom this type of treatment may be beneficial.

### Objectives

This review aims to answer the following questions about intrathecal pump systems, based on an analysis of the published literature.

- Which drugs and dosages are commonly used in clinical practice?
- How effective is this therapy compared with other treatments?
- What are the risks?
- What types of patients are suitable?
- How costly is this type of treatment compared with other treatments?
- What are the opinions of a group of UK pain specialists?

### Methods

Studies for inclusion in the review were obtained from standard medical databases and reference lists. All studies assessing the use of intrathecal pump systems in the treatment of chronic pain were included.

### Results

- A total of 114 studies, containing information on over 2000 patients, were identified.
- No randomised controlled studies or comparator studies were found. Data were extracted from case reports and case series-type information.
- The most commonly used intrathecal drug was morphine, followed by morphine in combination with bupivacaine. Dose escalation is an issue with this therapy, with reported dose increases of between 1% and 160% per week.
- A total of 53 studies were found that presented data on the effectiveness of pump systems. Sixteen of these reported visual analogue scores before and after pump usage. Average scores declined from 7.6/10 to 3/10 over a variable period of up to 2 years. All other measures of effectiveness, including various quality of life indicators, invariably reported positive effects.
- Risks of the therapy include pharmacological side-effects attributable to the drugs used (incidence 3–26% of patients) and mechanical complications associated with the pump delivery systems (incidence up to 20%).
- Patient selection criteria for this therapy are variously reported. The two main criteria are failure of or unacceptable side-effects from conventional therapy such as oral or subcutaneous opioids. A number of screening tests and trials of intrathecal therapy are used prior to actual pump implantation.
- The patient population receiving pumps is varied; some have cancer pain and some have non-cancer pain. Many will have tried numerous conventional treatments prior to intrathecal therapy; for others, with limited life expectancy and intractable pain, this is a “last resort therapy”. Two distinct patient types can therefore be identified: those with long life expectancy, but with resistant pain; and cancer

patients with limited life expectancy and intractable pain that is resistant to all other treatments.

- Costs and comparative costs are not widely reported. Some information from cost modelling and projections may indicate that the cost of this treatment is comparable or advantageous when compared with existing therapies, but this depends on individual patient circumstances.
- Opinions sought from 18 UK pain specialists revealed a split in opinion over the use of these pumps in clinical practice, with one-third being in favour of their use, one-third against and one-third undecided. This non-random sample contrasted with the generally positive reports in the published literature.

## Conclusions

No randomised, controlled or comparator data were found while carrying out this review. All information is therefore suboptimal. Published reports frequently use non-standard outcome measures on a heterogeneous patient population receiving different types of intrathecal pumps and drugs over varying periods. These variables make analysis very difficult.

However, such data as are available indicate a generally positive effect of the therapy, with side-effects and complications occurring in about a

quarter of the recipients, but it is difficult to draw definite conclusions because the quality of the data is so poor. Furthermore, the important clinical question: "Is this therapy any better than existing treatments?" is not answered by this review because of the lack of comparator data. The opinions from UK experts were not of such an overwhelmingly positive nature as the published reports.

## Recommendations for research

Further research is required to establish the place of this modality in the context of existing conventional treatments; a large multicentre randomised comparator trial could be used to assess the efficacy of intrathecal therapy compared with conventional therapies in the first group of patients noted above. A database or registry of intrathecal pump usage needs to be established to gather basic information collected when utilising standardised outcome measures for pumps used in patients in the second category, in whom randomisation may be inappropriate.

## Publication

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# NHS R&D HTA Programme

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Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme will continue to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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